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Original Article

Orthopaedics Section

Determination of Incidence of Soft Tissue Reactions after Total Hip Replacement using Elastography and Role of Elastography in Screening of Periprosthetic Soft Tissue: A Prospective Observational Study

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ABSTRACT

Introduction: Adverse local tissue reactions after Total Hip Replacement (THR) have been widely described in literature recently as a course of aseptic loosening. Evaluation for any adverse soft tissue reactions is challenging with traditional imaging techniques like Magnetic Resonance Imaging (MRI), and are limited, due to production of metallic artifact. Ultrasound, specifically its refined form elastography, has emerged recently as a useful tool for assessing the soft tissues.

Aim: To determine the incidence of soft tissue reactions in cases of THR and to evaluate role of elastography in assessment of periprosthetic soft tissue.

Materials and Methods: This prospective observational study was conducted in the Department of Orthopaedics at Dr. Hardas Singh Orthopaedic Hospital, Amritsar, Punjab, India, from May 2013 to April 2014. Study comprises of consecutively followed-up 66 hips which were evaluated and assessed clinically and radiologically using ultrasound elastography for periprosthetic soft tissue and degree of fibrosis. The MRI was done in patients with positive findings only. Diagnosis was then confirmed with biopsy in patients who underwent revision surgery. Incidence of clinical symptoms, implant loosening, stability of implant, various types of soft tissue reactions, pseudotumour formation and synovial hypertrophy were determined and association between clinical and radiological findings was done. Chi-square test was determined to see the statistical significance.

Results: Total of 66 hips were studied in 60 patients with mean age of 56.08±16.55 years (26-95 years). The incidence of soft tissue reactions observed in the study was 55 (83.3%), of all 66 hips 36 were symptomatic, implant loosening was seen in 29 hips, pseudotumours were detected in 3 (4.5%) hips, cystic nodules in 2 (3.0%) hips, enlarged lymphnodes in one (1.5%) hip, fibrogranuloma in 2 (3%) hips and synovial thickening was seen in 12 hips. Association of Harris Hip Score with capsular thickness, implant stability, acetabular loosening, joint congruency and degree of peritrochanteric fibrosis was found to be statistically significant.

Conclusion: The study shows a substantially higher incidence of soft tissue reaction and capsular hypertrophy following THR. Ultrasound elastography is a good screening tool to detect early soft tissue changes in periprosthetic tissue.

Keywords: Capsular hypertrophy, Elastography, Metal on metal, Metallosis, Pseudotumours

INTRODUCTION

Total Hip Replacement (THR) have evolved many folds over last few decades, using different combination of materials as an attempt to improve lifespan of prosthesis and reduce friction between articular surfaces. The main focus during this period was to reduce the incidence of aseptic loosening and osteolysis [1-3]. Recently various adverse local soft tissue reactions have been reported in THR leading to osteolysis, aseptic loosening and tumor formation, found particularly more with Metal on Metal (MoM) types [4-11].

Evaluation of periprosthetic soft tissue reactions in patients who underwent total hip arthroplasty is challenging. Use of most of traditional imaging techniques like Magnetic Resonance Imaging (MRI) are limited, due to production of metallic artifact [12]. Over the period ultrasound, specifically its refined form elastography, has emerged as a useful tool for assessing the soft tissues [13]. The purpose of the present study was to determine the incidence of soft tissue reactions in cases of THR and to evaluate role of elastography in assessment of periprosthetic soft tissue.

MATERIALS AND METHODS

This prospective observational study comprised of consecutive follow-up patients of THR who visited the outdoor facility of the Department of Orthopaedics, Dr. Hardas Singh Orthopaedic Hospital and Super-specialty Research Centre, Amritsar, Punjab, India, from May 2013 to April 2014. Permission for the study was taken by Institutional Ethics and Research Committee (IEC approval No.:2013/04/001) prior to the commencement of the study. Written informed consent was obtained from all the subjects enrolled in the study.

Inclusion criteria: All consecutive patients who had THR of two years or more were included in the study after they consented to be part of study.

Exclusion criteria: Patients with history of prosthetic dislocation or history of any infection in operated joint in postoperative period were excluded from the study.

Total of 66 hips were studied in 60 patients who were enrolled in the study. Power analysis of study was done using alpha error 0.05, effective size was calculated and the power achieved in our study was above 80%, hence sample size taken was considered to be adequate.

Data collection: All the patients underwent detailed clinical assessment including history, complaints if any, general and local clinical examination of the affected hip and stability of joint. The type of implant including liner, femoral head and femoral stem were documented.

- Basic haematological investigation like haemoglobin, Total Leukocyte Count (TLC), Differential Leukocyte Count (DLC) and Erythrocyte Sedimentation Rate (ESR) were done to rule out any active infection.
- Harris Hip Score was calculated to assess the overall function and was graded as [14,15]:

  <70=poor result;

  70-79=fair,

  80-89=good, and

  90-100=excellent
- Plain radiograph of pelvis with bilateral hips- Anteroposterior (AP) view and frog leg lateral view of the affected hip was taken and evaluated for loosening or lysis in acetabulum and femur.
- Loosening was assessed using Delee and Charnley's three zones for acetabulum [16] and Gruen's seven zones for the femoral component [17].

Ultrasound and Elastography

Routine ultrasound was performed for evaluation of operated hip. Transverse views in the region of groin anteriorly was taken to judge the position of implant and following features were ascertained:

- Status of the joint margins
- Thickness of joint capsule
- Any surrounding hypoechoic lesions/pseudotumour formation
- Status of visualised soft tissues

Ultrasound was followed by elastogram using same system with qualitative colour images of the periarticular soft tissues in which stiffness was assessed on colour scale with red as highly stiff, blue as least stiff and green as isoelasto. Quantitative Acoustic Radiation Force Impulse (ARFI) images were obtained and mean stiffness values of the soft tissues were determined in m/sec both adjacent to joint more than 2.5 cm (distance from joint). The patient was then made to lie in decubitus position and stiffness of soft tissue was determined in peritrochanteric region both qualitatively and quantitatively. Quantitative stiffness was determined by Shear Wave Velocity (SWV) in m/s and categorised as [Table/Fig-1]:

- Normal: <2 m/sec
- Mild Fibrosis (Grade I): 2-4 m/sec
- Moderate Fibrosis (Grade II): 4-6 m/sec
- Severe Fibrosis (Grade III): XX or not assessable

Stiffness Index was then calculated for normal and abnormal tissues.

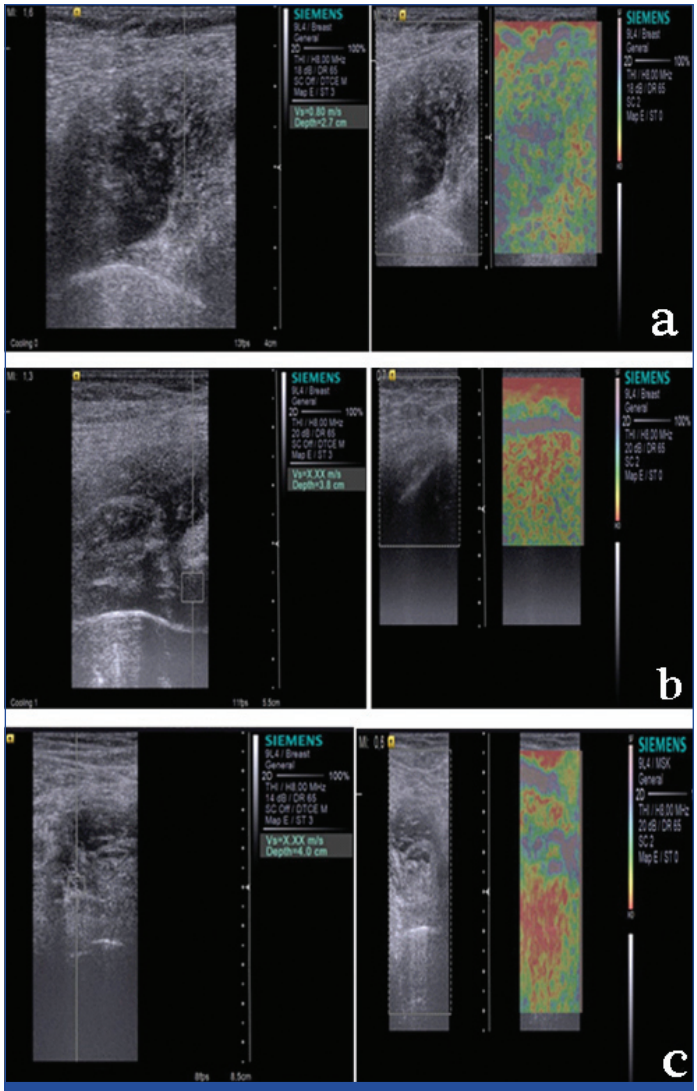
Magnetic resonance imaging: MRI was done in patients with positive findings, on SIEMENS 1.5 Tesla machine using surface coil, T1-Weighted Spin-Echo (T1WSE) and T2-Weighted Turbo Spin-Echo (T2WTSE) axial and coronal slices. Soft tissue changes especially fibrosis, pseudotumour formation were assessed. Diagnosis was then confirmed with biopsy in patients who underwent revision surgery or those who gave the consent for the same. Tissue obtained was subjected to histopathological examination.

STATISTICAL ANALYSIS

Data collected was tabulated using Microsoft Office Home edition and analysed using Statistical Package for Social Sciences (SPSS) version 17.0 software. Incidence of clinical symptoms, implant loosening, stability of implant, various types of soft tissue reactions, including pseudotumour formation and synovial hypertrophy were determined and association between Harris Hip Score and radiological findings was done. Chi-square test was determined to see if results generated were statistically significant (p-value <0.05).

RESULTS

Total of 66 hips were studied in 60 patients with mean age of 56.08±16.55 years (26-95 years). This study had 36 (54.5%) symptomatic and 30 (45.5%) asymptomatic hips with mean age of 60.42±16.87 years and 50.87±14.78 years for each group respectively.



[Table/Fig-1]: Images from elastography showing mild, moderate and severe fibrosis. (Left image): Quantitative stiffness index, (Right image): qualitative assessment of stiffness based on colour. a (Case No.30): Grade I-Mild Fibrosis. b (Case No. 8): Grade II-Moderate Fibrosis, c (Case No. 35): Grade III-Severe Fibrosis.

Femoral component loosening was detected in 8 (12.1%) hips while acetabular loosening was detected in 18 (27.3%) hips and 3 (4.5%) had signs of metalosis with cup migration, however acetabular loosening was seen in only one out of eight hips (12.5%) with MoM articulation. Four cases had both acetabular and femoral component loosening. In seven cases loosening of either acetabular or femoral component was detected but was found to be stable on comparison with previous radiographs [Table/Fig-2].

Minimum and maximum Harris Hip Score was found to be 6.80 (in a wheelchair bound patient due to other co-morbid conditions) and 99.85 respectively with mean Harris Hip Score of 76.905±24.92, and mean stiffness index was 1.818 (0.83-4.10) m/sec with SD 0.88.

Severe fibrosis was found in 9 of asymptomatic hips and 21 symptomatic hips, three of which had associated pseudotumour and one had loose bodies within joint. Moderate fibrosis was seen in nine of asymptomatic hips and in three symptomatic hips [Table/Fig-3].

Synovial/capsular hypertrophy was found in 12 (18.2%) out of 66 hips with mean capsular thickness of 2.079±1.48 (0.90-5.6) mm.

Quantitative elastographic assessment of hips in anterior part showed severe fibrosis in 19 (28.8%) hips out of 66, while 30 (45.5%) had moderate fibrosis and mild fibrosis was seen in 17 (25.8%) [Table/Fig-4,5].

Variables	n, %
Age (years) (Mean±SD)	56.08±16.55
Gender	
Male	37 (56.10%)
Female	29 (43.90%)
Side of joint studied	
Right	35 (57.6%)
Left	25 (42.4%)
Bilateral	6
Clinically symptoms	
Asymptomatic (number of hips)	30 (45.5%)
Symptomatic (number of hips)	36 (54.5%)
Pain	27
Limp	20
Shortening (1-5 cm)	21
Clicking Sensation	2
Grittiness	1
Foot drop	1
Duration of implant (months)	25-418 (Mean 93.56±83.13)
Type of articulation	
Poly on metal	56 (84.8%)
Metal on metal	8 (12.1%)
Ceramic on ceramic	2 (3%)
Acetabular component	
Cemented	37 (56%)
Uncemented	29 (44%)
Implant loosening	29
Femoral component	8 (12.1%)
Acetabular component	18 (27.3%)
Metalosis with cup migration	3 (4.5%)

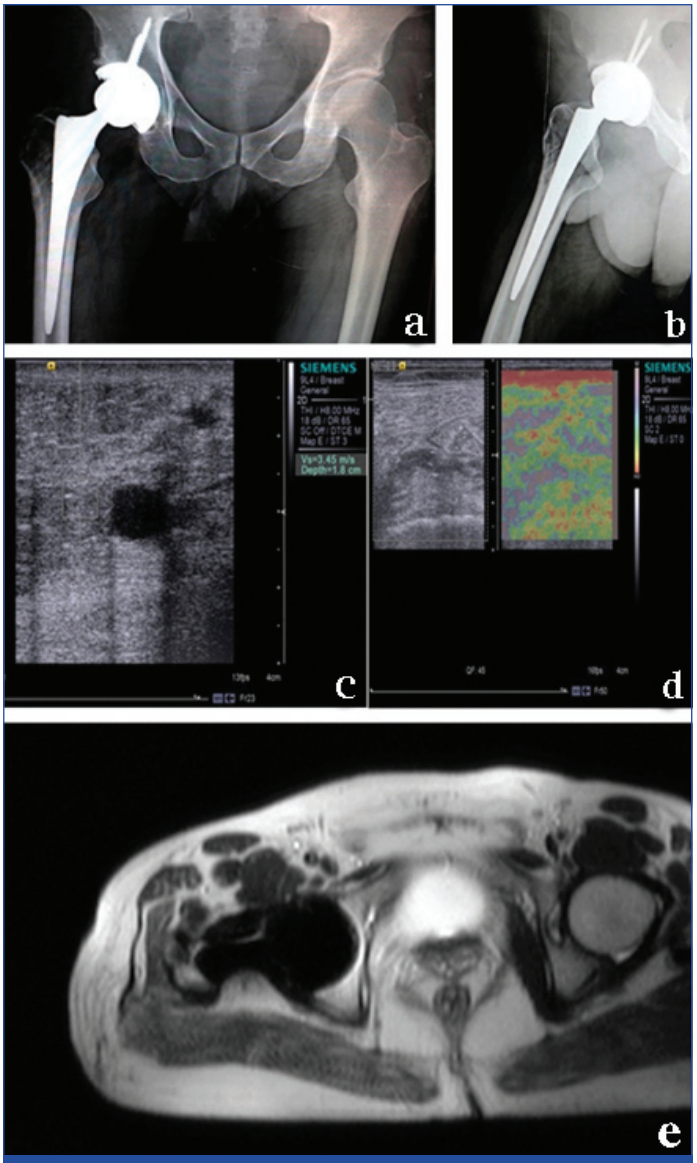
[Table/Fig-2]: Demographic distribution and Implant details.

Soft tissue reactions seen	Clinical symptomatology		Total
	Asymptomatic	Symptomatic	
Normal	6	5	11
Pseudotumours	0	3	3
Cystic nodules	2	0	2
Enlarged lymphnodes	0	1	1
Fibrogranuloma	1	1	2
Hypoechoic area	0	1	1
Hypoechoic shadows with fluid in gluteal sheath	1	0	1
Mild fibrosis	2	2	4
Moderate fibrosis	9	3	12
Severe fibrosis	9	17	26
Severe fibrosis with loose bodies within joint	0	1	1
Soft tissue calcification with moderate fibrosis	0	2	2
Total	30	36	66

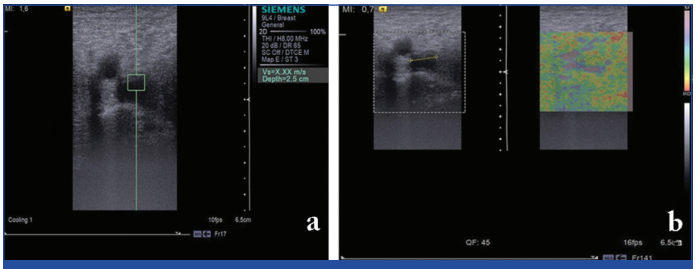
[Table/Fig-3]: Incidence of soft tissue reactions in symptomatic and asymptomatic patients.

Assessment of peritrochanteric area revealed severe fibrosis in 33 hips (50%) while 27 hips (40.9%) had moderate fibrosis and six hips (9.1%) had mild fibrosis.

Association of Harris Hip Score with implant stability, acetabular loosening, capsular thickness, joint congruency and degree of peritrochanteric fibrosis was found to be statistically significant [Table/Fig-6].



[Table/Fig-4]: a,b: X-ray of pelvis with both hips AP view and lateral view of right hip; c): Showing quantitative assessment of soft tissue around hip: Grade II Fibrosis; d): Qualitative assessment of soft tissue based on colour; e): MRI of same patient showing metal artifact in right hip region partially obliterating para-articular tissue.



[Table/Fig-5]: a): Elastographic image showing quantitative assessment of periprosthetic soft tissue; b): Elastographic images showing pseudotumor (Left) and Grade III fibrosis (Right).

Association of Harris Hip score with degree of fibrosis in symptomatic hips

Association of degree of fibrosis with Harris Hip Score was found to statistically significant for peritrochanteric region with p-value=0.005, however same association done for anterior region was found to be statistically insignificant (p-value=0.389).

Association of acetabular loosening with fibrosis in symptomatic hips

Association of acetabular loosening with degree of fibrosis seen on elastography in anterior and peritrochanteric regions was found to be statistically significant (p-value=0.043 and 0.041, respectively).

Harris Hip Score parameters		Harris hip score				Total (n=66)	Statistical analysis
		Poor (n=20)	Fair (n=5)	Good (n=10)	Excellent (n=31)		
Capsular thickness	Normal	12	5	8	29	54	χ^2:10.401, df:3, p-value=0.015
	Thick	8	0	2	2	12	
Implant stability	Stable	7	4	9	31	51	χ^2:30.412, df:3, p-value <0.0001
	Unstable	13	1	1	0	15	
Acetabular loosening	No loosening	4	4	8	29	45	χ^2:33.414, df:9, p-value <0.0001
	Loosening (Lucent zone >2 mm)	13	1	1	2	17	
	Cup migration	1	0	0	0	1	
	Metalosis	2	0	1	0	3	
Joint congruency	Congruent	14	5	9	30	58	χ^2:9.036, df:3, p-value=0.029
	Incongruent	6	0	1	1	8	
Degree of peri-trochanteric fibrosis	Mild	0	2	2	2	6	χ^2:18.374, df:6, p-value=0.005
	Moderate	6	2	1	18	27	
	Severe	14	1	7	11	33	

[Table/Fig-6]: Association of Harris Hip Score.
p-value <0.05 considered significant

Acetabular loosening	Clinical symptomatology		Total
	Asymptomatic	Symptomatic	
Absent	27	18	45
Present	3	15	18
Metallosis	0	3	3
Total	30	36	66

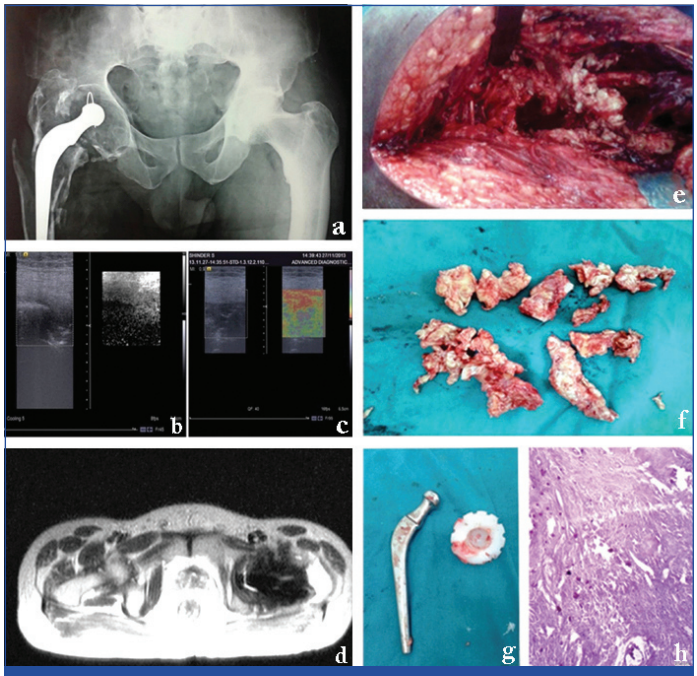
[Table/Fig-7]: Comparison of acetabular loosening in symptomatic and asymptomatic patients.
p=0.006; p-value <0.05 was considered as statistically significant

Fifteen of 36 symptomatic hips had acetabular loosening while other three of the symptomatic hips had metallosis. Rest 18 symptomatic hips did not have any acetabular loosening or signs of metallosis. Data was found to be statistically significant (p-value=0.006) [Table/Fig-7].

Case No.	Elastography				Biopsy	
	Degree of Fibrosis		Stiff-ness index	Conclusion based on elastography	Conclusion based on biopsy	
	Anterior	Peri trochanteric				
6	Grade II	Grade III	1.04	Pseudotumour	Fibrosis	Pseudotumour
9	Grade III	Grade III	XX	Severe fibrosis	Fibrosis	-
19	Grade II	Grade III	XX	Severe fibrosis	Fibrosis	-
24	Grade III	Grade II	1.12	Pseudotumour	Fibrosis	Pseudotumour
35	Grade III	Grade I	XX	Severe fibrosis	Fibrosis	-
41	Grade I	Grade III	0.83	Cystic nodules	Minimal fibrosis	-
43	Grade II	Grade II	XX	Moderate fibrosis	Fibrosis	-
44	Grade II	Grade III	XX	Severe fibrosis	Fibrosis	-
54	Grade III	Grade II	XX	Fibrogranuloma	Fibrosis	Vasculitis like lesion
58	Grade II	Grade II	2.3	Fibrogranuloma	Fibrosis	-

[Table/Fig-8]: Comparative table of elastography and biopsy.

Comparison of degree of fibrosis seen on MRI and biopsy: MRI was done in total of 41 hips (26 symptomatic and 15 asymptomatic), on analysis of data, soft tissue could be analysed in only 21 hips rest twenty had severe metallic artifacts which made analysis of soft tissue difficult. Open biopsy was done in 10 hips, which underwent removal of implant or revision, histopathology revealed presence of fibrosis with a good association between severity of fibrosis seen on elastography (p-value <0.001) along with pseudotumour in two hips [Table/Fig-8,9].



[Table/Fig-9]: (Case No. 24) a): Plain skiagram pelvis with both hips AP view showing severe osteolysis around femoral and acetabular component with deranged joint. b,c): Images from ultrasound and elastography with qualitative assessment. d): MRI Image of same patient showing severe metallic artefacts. e): Peroperative image of the same patient showing metallosis (Blackening). f): Tissue taken for biopsy from the area of suspected pseudotumour as located by MRI preoperatively. g): Recovered implant, UHMWPE acetabular cup with Stainless Steel femoral component (size XL). h): Histopathology image showing groups and sheaths of proliferating histiocytic cells and its bony trabeculae and fibroplastic proliferation.

DISCUSSION

Literature has widely described patients with failed MoM implants who had early asymptomatic implant loosening or had unexplained hip pain [18-24]. The most common cause for failure of implants of various types; traditional Poly on Metal (PoM) implants to different generations of MoM, have been attributed to the implant material which causes cascade of cellular events leading to osteolysis, loosening of implants and periprosthetic soft tissue reactions [6,7,25-27]. Histopathological evaluation of soft tissues around failed hip implants which were suggestive of inflammatory reactions and interpreted as representation of an immune reaction to metal particles or ions have also been described by several studies in recent past [28]. Adverse local soft tissue reactions after THR are not limited to MoM articulations only. Various studies have reported several cases of soft tissue reactions like perivascular and diffuse lymphocytic inflammation after non metal on metal articulations [8,9,11,26-29]. Few studies have been done in the recent past correlating the blood levels of different metals in MoM implants, using ultrasound, to study periprosthetic soft tissue reactions [30,31]. The idea of above studies was to determine the morphological changes

in and around the implant and to prognosticate patients who would eventually be held up with implant failure.

The incidence of soft tissue reactions observed in our study was 83.3% in patients with a mean age of 56.08 years and mean follow-up postimplantation of 93.5 months. This incidence was higher as compared to 54% in a study done by Nishii T et al., [32]. Possible reasons attributed to these can be nature of implant studied in the present study comprised 84% of PoM compared to 87 MoM implants and 21 Ceramic on Ceramic (CoC) implants in study done by Nishii T et al., Further second reason attributed to increased incidence in the present study could be due to increased resolution of the scanner along with increased sensitivity of elastoscan compared to ultrasound in determination of the soft tissue changes.

Since this study enrolled all the patients posthip replacement irrespective of centre where they were operated, including those who consulted at our centre for second opinion, comparable number of patients were found to be symptomatic. The most common symptom being pain (40.9%) followed by limp (30.3%). In the symptomatic group authors observed a very strong statistically significant association between the radiological findings of acetabular cup loosening. Similar results have been documented by various other authors regarding acetabular loosening [Table/Fig-10].

Study	Total number of hips (n)	Incidence of loosening	Mean follow-up
Hayter CL et al., [34]	29	7	31 months
Geir H et al., [7]	96	53	165 months
Present study	66	18	93.5 months

[Table/Fig-10]: Incidence of acetabular loosening compared to other studies.

To best of author's knowledge there have been no such study in literature which have categorised the degree of fibrosis and also shown the pattern of soft tissue reactions at two different periprosthetic sites. It is also pertinent to observe that the incidence of soft tissue reactions in post THR patients were comparable in our study in both symptomatic and asymptomatic patient groups. Similar results have been suggested by Pandit H et al., and Langton DJ et al., who suggested that many patients who developed soft tissue reactions were initially pain free but latter developed pain in implanted hip [25,31]. These studies also hypothesised that the soft tissue changes around the implant were result of the development of an immune cascade reaction to the release of implant debris, which continues for a significantly long period of time, as a asymptomatic phase until when this cellular cascade of events crosses a negative threshold point following which there is enhanced immune reaction, macrophagic activity leading to increased soft tissue reactions, osteolysis making patient symptomatic [25,27,31]. Another hypothesis was suggested by Ollivere B et al., who suggested peri-implant vasculitis as one of the mechanism leading to tissue necrosis [30]. Langton DJ et al., based on the above hypothesis suggested determination of serum cobalt and chromium levels in patients with MoM implants and concluded that levels above 7 µg/L, irrespective of being symptomatic or asymptomatic, has an increased potential for soft tissue reaction around the implant thereby leading to failure. Author also suggested that such patients are also not good candidates for MoM resurfacing surgeries [31].

Since in Indian clinical scenario as of date it is not easily possible to get blood chromium and cobalt levels in such patients primarily either due to lack of availability and/or cost, moreover a large number of follow-up comprises of non metal on metal implants were observed in the present study therefore findings of this study also highlights the potential role and usefulness of doing elastography in all patients of hip implants of all types to determine the presence and absence of soft tissue reaction to grade the severity of fibrosis, so that patients with increased likelihood of implant failure could be categorised.

Various reports have described high rates of osteolysis, loosening and higher incidence of radiolucent line/impending failures in different types of articulation with highest incidence in MoM type of articulation [7,33,34]. Geir H et al., reported high wear rates along with extensive osteolysis with poor long term survival rates in THR, author had reported moderate to extensive osteolysis in 46 out of 96 hips [7]. Present study shows incidence of 18 (27.3%) overall loosening of acetabulum irrespective of type of articulation. Present study also shows acetabular loosening in only one out of eight hips (12.5%) with MoM articulation. Haddad FS et al., reported hypersensitivity to N,N-Dimethyl-p-toluidine, a component of bone cement, to be one of the causes of extensive or early osteolysis or failure in cemented hips.

Finite element analysis has shown the principle stresses generated in the normal acetabulum are to be aligned with the orientations of the trabeculae. These patterns of stress transmission are distinctly changed after total hip replacement, with increase in the compressive forces in the cancellous region immediately superior to the cup, and increase in tensile stress in medial wall of illium, in cement and in the acetabular cup, so increasing the stiffness of the acetabular cup would reduce the magnitude of peak stress within surrounding bone and cement, which can be achieved by retaining subchondral bone, increasing the thickness of bone cement or polyethylene liner or by using metal backed component [6,35-37]. Various studies have shown that adding metal backing to polyethylene liner has better outcomes [11,21,37,38]. Authors conclude that reason for loosening might be related to sensitivity to metal ions as well as high mechanical stress or to the hypersensitivity to components of bone cement which requires further study with a large group possibly in a multicentric type of trial so that histopathological confirmation of the same can also be done.

In comparison to the findings seen on elastography, the MRI findings of the soft tissues in the symptomatic group showed findings in only 10/18 hips i.e. 55.5% compared to fibrosis seen in all of the eighteen hips on elastography (100%). The results when compared to the study done by Nishii T et al., were also comparable as in this study ultrasound and MRI detected soft tissue changes in 54% of the symptomatic patients [32]. Open biopsy was done in 10 patients who underwent revision. All 10 patients showed presence of fibrosis on histopathological examination with a good association between severity of fibrosis seen on elastography (p-value <0.001). All of them showed severe fibrosis with two patients showing pseudotumour formation and vasculitis like lesion was seen in one patient. However, no accurate conclusion could be derived, due to limited number of biopsy.

It is suggested that, a further long term study with large number of patients is needed to ascertain statistical association between MRI and elastography and to prognosticate the implication of fibrosis posthip replacement.

Limitation(s)

Present study was limited by lower number of histopathological specimen due to which authors were unable to confirm whether the synovial hypertrophy seen on ultrasound and elastography is particle-induced or secondary to micro motion. It was observed that soft tissue changes which were discernible with confidence were only those showing peri-implant pseudotumour formation, fibrogranuloma or cystic collections. The present study was constrained by limited number of histopathological correlations of radiological findings, mainly as either patients were asymptomatic and/or did not give consent for biopsy, being an open surgical procedure. Due to above limitations, no accurate statistical association could be established with the elastography findings. This study also falls short of determining interobserver variation between the estimation of different radiological findings. Another potential limitation of the study could be small number of patients

i.e. 66, which has potential to infer the statistical significance of the results obtained if done on a large group.

CONCLUSION(S)

The present study has substantially higher incidence of soft tissue reaction and capsular hypertrophy following THR. Authors recommend close monitoring of all the patients with THR for early detection of soft tissue reactions. It is also recommended for the patients with early signs of loosening or radiolucency, who are otherwise stable should be kept under close monitoring. It is concluded that elastography is a good tool for the screening of soft tissue changes in periprosthetic tissue when compared with MRI in assessment of soft tissue reactions in patient with hip prosthesis.

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