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**Research Article** 

# Comparative mid-term evaluation of unilateral and bilateral total knee arthroplasty utilizing metal-backed components: An assessment of functional and clinical outcomes

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# ABSTRACT

*Objective*: This prospective, post-marketing surveillance (PMS) study (Freedom 400) aimed to evaluate the clinical and functional outcomes of both unilateral and bilateral total knee arthroplasty (TKA) utilizing cruciate retaining/posterior stabilized (CR/PS) implants with metal-backed components (MBC). *Methods*: Between November 2016 to January 2019, 408 patients underwent either unilateral or bilateral TKA at ten centers across India. Patients with primary end-stage osteoarthritis (OA) or inflammatory arthritis were included whereas, revision TKA patients were excluded from the study. Primary endpoints were 3-year implant survivorship and revision rates, with secondary endpoints including range of motion (ROM), Knee Society Score (KSS), and quality of life (QoL) assessed through WOMAC and SF-36 at 6 weeks, 6 months, 1- and 3 years. *Results*: The study comprised 242 unilateral and 166 bilateral TKA patients, with an average age of 65.13  $\pm$  8.35 and 64.34  $\pm$  7.25 years, respectively. Both groups exhibited a mean body mass index of 27.13  $\pm$  4.73 kg/m<sup>2</sup> and 27.80  $\pm$  4.41 kg/m<sup>2</sup>. Female patients dominated the groups: 78.1 % and 86.75 % respectively, and the primary

diagnosis was OA: 97.11 % and 96.39 %, respectively. Significant ROM improvement was observed in both

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groups (p < 0.001). Notable improvement was seen from baseline in mean clinical KSS (bilateral:  $33.28 \pm 15.84$  to  $91.06 \pm 8.52$ , p < 0.001; unilateral:  $31.26 \pm 15.7$  to  $92.43 \pm 8.07$ ) and functional KSS (bilateral:  $30.17 \pm 21.19$  to  $98.50 \pm 4.08$ , p < 0.001; unilateral:  $26.59 \pm 21.25$  to  $98.41 \pm 4.33$ , p < 0.001) at 3 years. Baseline WOMAC scores among both the groups showed higher pre-operative values (25.78 and 23.91) which significantly lowered for pain (scores: 1.16 and 1.46), stiffness (scores: 0.53 and 0.68) and physical function (scores: 2.89 and 3.1) at 3 years indicating improved QoL. Similar significant trend was noted for SF-36 assessment (p < 0.001) in both the groups.

*Conclusion*: This PMS study concluded that unilateral and bilateral TKA using MBC yielded good outcomes and there was a significant improvement in ROM, KSS scores and QoL in patients with osteoarthritis-associated joint degeneration.

Abbrevi	ations:					
AP	All polymer					
BTKA	Bilateral total knee arthroplasty					
CR	Cruciate retaining					
KSS scor	KSS scores Knee society scores					
LOS	Length of stay					
MBC	Metal backed components					
OA	Osteoarthritis					
PS	Posterior stabilized					
QoL:	Quality of life					
ROM	Range of motion					
TKA	Total knee arthroplasty					
UTKA	Unilateral total knee arthroplasty					
WOMAC scores Western Ontario and McMaster Universities						
	Osteoarthritis Index					

## 1. Introduction

Total knee arthroplasty (TKA) is a well-established surgical intervention, characterized by an success rate of approximately 92 %.<sup>1</sup> This procedure, renowned for its efficacy in managing end-stage osteoarthritis (OA), exhibits a distinct prevalence, with a higher incidence observed among females (13 %) than males (10 %).<sup>2</sup> Total knee arthroplasty procedures can be either unilateral (UTKA) or bilateral (BTKA), with the latter further categorized as simultaneous or staged. The decision-making process between unilateral and bilateral TKA is of paramount importance, as it profoundly impacts patient outcomes, contingent upon the degree and lateralization of joint involvement. Simultaneous BTKA is associated with heightened complication rates, encompassing increased intraoperative blood loss, the necessity for perioperative blood transfusions, elevated incidences of venous thromboembolism, cardiorespiratory issues, neurological manifestations, wound dehiscence, and deep-seated infections.<sup>3–9</sup> Conversely, staged BTKA procedures mitigate complication rates but are correlated with augmented inpatient expenditures.5-7 However, opting for UTKA appears to yield more favorable outcomes.3,6

With continuous improvements in the design of the prosthesis components, attaining optimal range of motion (ROM) along with significant bone preservation is possible.<sup>10,11</sup> While determining the optimal implant, the most desirable factors are prosthesis stability, patient's satisfaction and cost-effectiveness.<sup>11</sup> The leading prosthetic devices adopted extensively are the cruciate retaining (CR) and posterior stabilized (PS) implants, which are meticulously designed to closely replicate the natural biomechanics of the knee joint.<sup>10,11</sup>

The CR and PS knees are available in both all polymer (AP) as well as metal backed (MB) components.<sup>12,13</sup> In a systematic review of 68,202 TKAs in 2017, comparing AP to MB tibial component outcome scores, a notable distinction favored the MB component in terms of Knee Society

Score functional outcomes (KSS-F).<sup>12</sup> Studies show that AP tibial components displayed high failure rates of up to 17 % within two years which is not seen with MB tibial component. Despite higher cost and complications like osteolysis and wear,<sup>13</sup> metal backing offers potential advantages such as decreased bending strains in the stem and uniform distribution of eccentric loads across the entire underlying tibial surface.<sup>12,13</sup> Despite comparable clinical outcomes and knee motion ranges to their AP counterparts, MB tibial components in TKA exhibit superior long-term survival, boasting lower rates of complications and revisions.<sup>14</sup> Consequently, surgeons lean towards MB components, prioritizing them over AP options in TKA procedures to mitigate potential complications and enhance overall outcomes.<sup>14</sup>

The primary objective of our study was to evaluate the mid-term success rate, functional outcomes, complications, and implant stability associated with CR/PS implants in the context of both unilateral and bilateral TKAs utilizing MB components.

## 2. Methods

# 2.1. Study design

A prospective, single-arm post-marketing surveillance study (Freedom 400 study, CTRI no: CTRI/2016/11/007455) was conducted across multiple centers (10 sites) in India (November 2016-January 2019) to compare the outcomes of unilateral and bilateral TKA, both utilizing MB components of CR/PS knee implants (Freedom total knee system, Maxx Orthopaedics Inc., Plymouth Meeting, Pennsylvania, USA). The study was approved by the local ethical committee review board at each site. Prior to their involvement, all subjects provided signed informed consent. Patients underwent assessments before the surgery and at intervals of 6 weeks, 6 months, 1 year, and 3 years postoperatively. These assessments included a thorough examination of medical history, physical condition, and radiographic imaging. The primary endpoints of the study involved determining implant survivorship and calculating the cumulative revision rate. Secondary endpoints included the KSS for pain both functional and clinical assessment, ROM for functionality and mobility of the knee, and stability, Western Ontario and McMaster Universities Osteoarthritis (WOMAC) score, and Short Form Health (SF-36) questionnaires scores for physical and mental health.

# 2.2. Eligibility criteria

## 2.2.1. Inclusion criteria

- Patients diagnosed with end-stage Kellgren-Lawrence (KL) Grade IV osteoarthritis or inflammatory arthritis in one or both knees, with or without associated deformities,
- 2. Non-pregnant female and male >18 years of age at the time of study,
- 3. Patients capable of providing written and signed consent in the informed consent form.

### 2.2.2. Exclusion criteria

1. Patients undergoing revision surgery,

- 2. Patients unable to provide written informed consent,
- 3. Patient with end-stage illness (such as cancer, AIDS) with short-life expectancy of <5 years, were excluded from the study.

## 2.3. Statistical analysis

The results are presented as the mean value  $\pm$  standard deviation for continuous variables, and as the number and percentage for nominal variables. Paired *t-test* for dependent samples is used to compare continuous variables utilizing Version 15 of the Statistical Package for Social Sciences (SPSS, Chicago, IL, USA). The results are statistically significant with a p-value of less than 0.05.

# 3. Results

A total of 408 patients were enrolled of which 242 patients underwent UTKA and 166 patients underwent BTKA. The average age of patients in unilateral group was  $65.13 \pm 8.35$  years and in bilateral group was  $64.34 \pm 7.25$  years. Mean body mass index among both groups were  $27.13 \pm 4.73 \text{ kg/m}^2$  (unilateral patients) and  $27.80 \pm 4.41 \text{ kg/m}^2$ (bilateral groups). The unilateral group comprised 189 (78.10 %) females and 53 (21.90 %) males, similarly bilateral group was dominated by 144 (86.75 %) females and 22 (13.25 %) males. The primary diagnosis was osteoarthritis in both the groups (unilateral group: n = 235[97.11 %] and bilateral group: n = 160 [96.39 %]), while inflammatory arthritis was diagnosed in 4 patients each in both the groups. Fig. 1 gives the details of baseline and demographic characteristics of both unilateral and bilateral patients. The patients presented with various comorbid conditions, with hypertension being the dominant comorbidity in both groups (unilateral group: n = 113 [46.69 %] and bilateral group: n = 82[49.40 %]) followed by diabetes mellitus (n = 38 [15.7 %] and n = 30 [18.07 %], respectively). The medical history of patients is described in Fig. 2. Fig. 3 gives the details of total knees implanted in both unilateral and bilateral TKA groups. All patients underwent comprehensive radiographic evaluations before the surgery and during follow-ups.

Eight patients withdrew from the study at 3 years follow up after undergoing UTKA, whereas, during the 3-year study period, 7 patients withdrew from the study in BTKA group. One UTKA patient passed away three years post discharge, but the primary cause of death was unknown, whereas in BTKA group, four patients died post discharge due to lung infection, pneumonia and cardiac arrest. Table 1 depicts the comparison and adverse events between the unilateral and bilateral TKA groups. Mortality rates were higher among females (0.9 %) as compared to males in both groups.

In our study, ROM outcomes were rigorously assessed to determine the efficacy of the CR/PS MBC implants in restoring joint functionality and improving patient mobility in both UTKA and BTKA groups. The mean pre-operative ROM of the knee joint in the BTKA group was 94.92°  $\pm$  18.23° which improved consistently to 122.88°  $\pm$  4.85° at the final follow up of 3 years. In the UTKA group, the mean ROM improved from 95.62°  $\pm$  19.69° (pre-operatively) to 122.38°  $\pm$  5.86° at the 3-year follow up, achieving a significant level of improvement in both the groups (p < 0.001) (Table 2). The radiographs of pre-operative OA knees and the post-operative MBC implant during the three-year study period are depicted in Fig. 4 (panels A-E).

Patient satisfaction assessed through KSS (clinical and functional) to thoroughly evaluate the post-operative improvements in knee function was performed at all follow-up time intervals. There was no statistically significant difference in clinical and functional KSS outcomes between unilateral and bilateral TKA. The mean clinical KSS for bilateral TKA patients was  $70.63 \pm 14.22$  at 6 weeks and  $91.06 \pm 8.52$  at 3 years, (p < 0.001) while functional KSS improved from  $71.21 \pm 15.40$  at 6 weeks to  $98.50 \pm 4.08$  at 3 years (p < 0.001). Conversely, the mean clinical KSS improved for UTKA patients from  $31.26 \pm 15.7$  at baseline to  $92.43 \pm 8.07$  at the 3 years follow up (p < 0.001). Similarly, the mean functional KSS also showed improvement from pre-operative  $26.59 \pm 21.25$  score to  $98.41 \pm 4.33$  at 3 years follow up (p < 0.001) (Table 3).

The quality of life of patients in both groups improved substantially post-operatively, gradually improving at all follow-up time points as assessed by SF-36 questionnaire and WOMAC scorings. Patients reported experiencing significantly less or no pain at the 3 years mark as opposed to the pre-operative (p < 0.001) assessment. Additionally, both cohorts exhibited substantial reductions in post-operative stiffness and significant improvements in physical function. The substantial improvement in overall WOMAC scores indicates continuous and sustained progress in both the UTKA and BTKA groups over the years.



Fig. 1. Baseline and demographic data of unilateral and bilateral TKA patients implanted with metal backed components.



Fig. 2. Distribution of co-morbid diseases in unilateral and bilateral TKA patients implanted with metal backed components. (DM: Diabetes mellitus; CAD: Coronary artery disease; COPD: Chronic obstructive pulmonary disease).



Fig. 3. List of total metal backed knees implanted in unilateral and bilateral patients.

#### (Table 4).

The evaluation of QoL post-operatively was also assessed by SF-36 questionnaire score, which demonstrates improvement in physical as well as mental health and decrease in pain irrespective of unilateral or bilateral TKA procedures. The overall rate of revisions was 0 % for patients of both the groups (Table 5).

# 4. Discussion

The significant impact of MB components in this comparative study between UTKA and BTKA is evident in the mid-term outcomes. Radiographic evaluations and the absence of revisions during the three-year follow-up suggest the durability and stability of MB components, highlighting the safety profile and reliability of the implant. This aligns with recent literature highlighting the low revision rates associated with contemporary knee implant designs, including MB components. <sup>15,16</sup> In a

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#### Table 1

Complications and mortality ratio in unilateral and bilateral TKA patients implanted with metal backed components.

Reason for serious adverse events	Unilateral group	Bilateral group
Death		
Unknown reason	1	2
Pneumonia	-	1
Hyperkalaemia	-	1 <sup>a</sup>
Acute renal failure	-	1 <sup>a</sup>
Congestive cardiac failure	-	1 <sup>a</sup>
Bradycardia	-	1 <sup>a</sup>
Orthopnoea	-	1 <sup>a</sup>
Metabolic acidosis	-	1 <sup>a</sup>
Mortality (Female: male) ratio	1:0	3:1
Other adverse reasons		
Skin rash below knees	-	1
Suture Line Abscess	1	-

<sup>a</sup> An 82.6-year-old male patient with multiple baseline co-morbidities got readmitted for metabolic acidosis with hyperkalaemia with bradycardia 6 weeks post-TKA. He was admitted under cardiac care but unfortunately the patient expired the next day due to cardiopulmonary arrest.

retrospective, single-center study assessing the clinical outcomes of MBC, a revision rate of 2.5 % was observed.<sup>15</sup> Additionally, MB tibias are shown to be significantly superior to AP tibias regarding anterior–posterior rotation, and internal–external rotation.<sup>16</sup>

The comprehensive demographic data demonstrates an equitable distribution across age categories, with an average age of  $65.13 \pm 8.35$ 

vears in the unilateral group and  $64.34 \pm 7.25$  years in the bilateral group. Furthermore, the study cohort displayed a BMI range typical for TKA candidates, enhancing the generalizability of the study findings. Our data reveals a higher representation of females undergoing TKA. This finding substantiates the well-documented trend of a greater proportion of women seeking TKA, aligning our study with the established body of knowledge in the field. <sup>17–19</sup> The prevailing diagnosis across both cohorts was knee OA, underscoring the uniform application of TKA as a therapeutic intervention for addressing degenerative joint pathologies.<sup>20–22</sup> Our results are consistent with the extensive literature on TKA outcomes, as evidenced by prior studies.<sup>1-4,19-24</sup> These investigations have collectively enriched the body of knowledge affirming the efficacy of TKA, especially in mitigating joint degeneration associated with OA. The confirmed success of TKA in our study, coupled with existing research, reinforces the robust evidence supporting the ongoing use of this surgical approach for the management of degenerative joint conditions.

The high prevalence of comorbidities, particularly hypertension and diabetes mellitus, further underscores the necessity for meticulous perioperative management. These comorbidities can significantly impact post-operative outcomes, emphasizing the importance of thorough consideration and intervention, as previously highlighted in the literature.<sup>23,24</sup> In a retrospective study conducted at a single center, consecutive propensity score matching utilizing all baseline characteristics as covariates, was conducted to evaluate TKA outcomes in patients with and without diabetes mellitus. The findings revealed that patients

## Table 2

Range of motion data in unilateral and bilateral TKA patients implanted with metal backed components.

Range of motion (degrees)'	Pre-operative	6 weeks	6 months	1 year	3 years	p-values (pre-operative vs. 3 years)
Unilateral group	$95.62 \pm 19.69$	$111.62\pm12.2$	$113.41 \pm 12.76$	$115.\pm11.47$	$122.38\pm5.86$	<0.001
Bilateral group	$\textbf{94.9} \pm \textbf{18.23}$	$105.62\pm13.47$	$111.46\pm10.77$	$113.12\pm10.01$	$122.88\pm4.85$	< 0.001



Fig. 4. Panel A—The antero-posterior (AP) view of the diseased knee; Panel B— shows the lateral view of the diseased knee; Panel C shows the AP view of the implanted knee; Panel D and E shows the lateral and skyline view, respectively of the post-operative MBC implant during the three-year study period.

Table 3

Knee Society Score (KSS) in unilateral and bilateral TKA patients implanted with metal backed components.

Follow-Up	Unilateral group	teral group p-values (baseline vs. 3 years)		p-values (baseline vs. 3 years)		
Clinical KSS, mean ± SD				<0.001		
Baseline	$31.26 \pm 15.7$		$33.28\pm15.84$			
6 weeks	$71.68 \pm 15.53$		$70.63 \pm 14.22$			
6 months	$\textbf{78.28} \pm \textbf{14.53}$		$79.9\pm10.78$			
1 year	$84.36 \pm 11.19$		$83.38 \pm 9.17$			
3 years	$92.43 \pm 8.07$		$91.06\pm8.52$			
Functional KSS, mean $\pm$ SD						
Baseline	$26.59\pm21.25$		$30.17\pm21.19$	< 0.001		
6 weeks	$\textbf{74.97} \pm \textbf{20.19}$		$71.21 \pm 15.40$			
6 months	$80.95 \pm 17.03$		$83\pm12.23$			
1 year	$88.56 \pm 12.67$		$88.79 \pm 10.31$			
3 years	$98.41 \pm 4.33$		$98.5\pm4.08$			

#### Table 4

WOMAC Score in unilateral and bilateral TKA patients implanted with metal backed components.

Variables	Follow-up	Unilateral group	p-values (baseline vs. 3 years)	Bilateral group	p-values (baseline vs. 3 years)
Pain	Baseline	25.78		23.91	<0.001
	6 weeks	10.92		9.75	
	6 months	6.15		6.01	
	1 year	3.71		3.54	
	3 years	1.16		1.46	
Stiffness	Baseline	6.69		6.19	< 0.001
	6 weeks	2.94		2.7	
	6 months	1.57		1.4	
	1 year	0.96		0.77	
	3 years	0.53		0.68	
Physical Function	Baseline	55.1		49.87	< 0.001
	6 weeks	24.16		21.09	
	6 months	13.98		13.66	
	1 year	8.54		8.08	
	3 years	2.89		3.1	

Table 5

SF-36 Questionnaire scores in unilateral and bilateral TKA patients implanted with metal backed components.

Parameter	Follow-up	Unilateral group	p-values (pre-operative vs. 3 years)	Bilateral group	p-values (pre-operative vs. 3 years)
Physical functioning	Pre-operative 6 weeks	11.56 57.04		11.51 57.04	<0.001
	6 months	72.84		72.84	
	1 -year	75.49		75.49	
	3 years	73.22		73.32	
Emotional well being	Pre-operative	64.75		64.76	< 0.001
	6 weeks	73.46		73.46	
	6 months	78.07		78.07	
	1 -year	79.8		79.8	
	3 years	77.59		77.59	
Pain	Pre-operative	31.58		31.58	< 0.001
	6 weeks	64.76		64.76	
	6 months	74.06		74.06	
	1 -year	81.33		74.06	
	3 years	84.18		84.18	
Health change	Pre-operative	24.7		24.7	< 0.001
	6 weeks	80.49		80.49	
	6 months	88.73		88.73	
	1 -year	92.28		92.28	
	3 years	89.24		89.24	

diagnosed with diabetes experienced a prolonged duration of stay after surgery, notably for those with a length of hospital stay (LOS) exceeding three days (66.7 % vs. 50 %, P = 0.028). Moreover, this group exhibited a reduced ROM post-surgery compared to their non-diabetic counterparts (106.43  $\pm$  7.88 vs. 109.50  $\pm$  6.33°, p = 0.011).<sup>23</sup> In another study examining the LOS and cost effectiveness revealed that patients with many comorbidities used more resources and had a longer LOS.<sup>24</sup> Although we did not specifically analyze the impact of comorbidities like diabetes, LOS for patients in each cohort was less than 3 days in average.

The substantial post-operative improvement in ROM, exceeding 120°, in both unilateral and bilateral groups provide compelling evidence for the positive influence of MB components on joint function highlighting the efficacy of the study implant. A detailed examination of 95 cases of total knee joint replacement revealed a noteworthy enhancement in patients with initially limited pre-operative flexion (101.6 ± 14.3°), with post-operative flexion scores significantly increasing to  $106.3 \pm 11.1^{\circ}$  (p-value <0.001)<sup>25</sup> which is slightly lower than the scores observed in our cohorts.

Similarly, clinical and functional KSS improvements in both groups further endorse the effectiveness of the study implant. The absence of significant differences between patient's scores in both unilateral and bilateral groups demonstrates the versatility of CR/PS knees, accommodating diverse surgical approaches without compromising outcomes. This aligns with findings from recent literature emphasizing comparable functional outcomes between unilateral and bilateral TKA.<sup>26,27</sup> The improvement in quality of life, as assessed by SF-36 and WOMAC scores, highlights the holistic benefits of MBC in mitigating pain, reducing stiffness, and enhancing patients' overall well-being. A cross-sectional study involving 118 patients was undertaken to assess health related QoL, functional status, and related characteristics before and after undergoing TKA over a duration of 3–12 months.<sup>28</sup> The primary factors influencing the QoL in patients were identified as gender and age. The crucial factors for measuring improvements in QoL were found to be function and discomfort.<sup>28</sup> Following the TKA operation, there was a significant improvement. In another prospective study, patients were monitored for a duration of 12 months post-TKA, revealing noteworthy improvement (p < 0.001) post-surgery examined utilizing WOMAC, KSS ratings.<sup>26</sup> Female patients exhibited lower QoL scores both before and six weeks after undergoing TKA.<sup>26</sup> We did not notice any such disparities in WOMAC, KSS scoring including SF-36 scores in female patients. They experienced significant improvement over 3 years study period despite their poor baseline scores similar to other published literatures.<sup>28</sup>

# 5. Limitations

This study has several limitations. Firstly, the study may lack generalizability due to an uneven distribution between unilateral and bilateral TKA patients, with a higher representation of unilateral cases. Additionally, the male-to-female ratio is uneven, with females being the predominant factor in our study. The withdrawal of some patients during the follow-up period could introduce bias and affect the completeness of the data, potentially impacting the overall interpretation of the results. Another limitation lies in the relatively moderate duration of our follow-up period of three years, which may restrict the comprehensive evaluation of long-term implant survivorship and outcomes. To comprehensively assess the long-term efficacy, performance, and survivorship of the knee implant, it is imperative to conduct a study with an extended follow-up duration, ideally spanning 5–10 years.

## 6. Conclusion

Despite the limitations, the study contributes valuable insights into the comparative effectiveness of unilateral and bilateral TKA. Both procedures utilizing metal-backed components demonstrated comparable success rates and favorable outcomes, supporting the viability of these approaches in addressing degenerative knee disorders. The absence of revisions in both unilateral and bilateral TKA groups over the three-year span underscores the stability and reliability of the implants within this short-term evaluation. This suggests the durability and stability of CR and PS implants with metal-backed components. The study reveals notable improvements in ROM, clinical and functional KSS, WOMAC scores, and SF-36 questionnaire scores for both unilateral and bilateral TKA. These positive trends in functional outcomes and quality of life metrics highlight the effectiveness of the chosen implants in enhancing postoperative patient well-being.

# CRediT authorship contribution statement

Ponnanna Karineravanda Machaiah: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. Supreet Bajwa: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. Ravi Teja Rudraraju: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing original draft, Writing - review & editing. Kunal Aneja: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing - review & editing. Haresh P. Bhalodiya: Conceptualization, recruited the patient, Supervision, Validation, Writing – review & editing, Rakesh Kumar Singh: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Vividh Makwana: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Avtar Singh: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Vivek Logani: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Buddhadev Chatterjee: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Devendra S. Solanki: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Hemant Wakankar: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Sanjeev Mahajan: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Chandra-Shekhar Yadav: Conceptualization, recruited the patient, Supervision, Validation, Writing - review & editing. Ashokkumar Thakkar: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing original draft, Writing - review & editing. Udita Chandra: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing - original draft, Writing – review & editing. Sanaa Ansari: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. Shivadharshni Sivakumar: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing, All authors have reviewed and approved the final version of the article for publication.

## Informed consent statement

All study participants or their legal guardian provided informed written consent about personal and medical data collection prior to study enrolment.

## Statement of informed consent

Written informed consent was obtained from all enrolled patients and the Local ethics committee at each site approved the study to be conducted at their centers.

# Submission declaration

All authors declare that the article is not under consideration for publication elsewhere, that all authors take the responsibility of the data and content of the article. All authors give their consent for publication and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

## Data sharing statement

The original dataset is available along with the article as graphs and tables.

## Institutional review board statement

The study was reviewed and approved by the local Institutional Review Boards at respective sites.

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## Declaration of competing interest

Dr. Ashokkumar Thakkar, Dr. Udita Chandra, Ms. Sanaa Ansari and Ms. Shivadharshni Sivakumar are full-time employees of Meril Life Sciences Pvt. Ltd. Vapi, Gujarat, India. All other authors have no conflict of interest to declare related to the manuscript.

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