Original Article

Clinical Profile and Treatment Outcomes in Patient with Acromegaly Using 14th Acromegaly Consensus Criteria

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Abstract

Introduction: Acromegaly is a chronic systemic disease characterized by excessive secretion of growth hormone (GH) and insulin-like growth factor 1 (IGF-1). This study reviews our experience with endoscopic transsphenoidal surgery (TSS) in acromegaly patients, focusing on remission rates according to the 2023 consensus criteria. **Methods:** We conducted a hospital based, retrospective study involving 42 patients diagnosed with acromegaly who underwent endoscopic TSS, between January 2020 and June 2024. Clinical and hormonal profiles, comorbidities and outcome data were analysed. Remission was defined as age-adjusted IGF-1 levels 3 months post-surgery. **Results**: Mean age at diagnosis was 36.43 ± 10.70 years. The two most frequent presenting symptoms were headache (64.28%) and visual deficits (47.61%). Common comorbidities included diabetes mellitus (23.8%) and hypertension (28.57%). Pre-operative hormonal evaluation revealed secondary hypogonadism in 41.66% of patients, followed by hypothyroidism (23.81%) and cortisol deficiency (21.43%). Biochemical remission was achieved in 18 out of 42 patients (42.85%), including all five patients with microadenomas and 35.13% of those with macroadenomas. Although Knosp grade, maximum tumour diameter and pre-operative post glucose growth hormone levels showed significant associations in univariate analyses, these associations were not significant after adjustment. On multivariate analysis, post-operative day 2 GH levels (≤2.75 ng/ml) emerged as a significant predictor of remission. **Conclusions**: This study provides the comprehensive review of clinical presentations and outcomes of patients with acromegaly based on the latest acromegaly consensus guidelines. Notably, a post-operative day 2 GH less than 2.75 ng/ml emerged as a significant predictor of outcome.

Keywords: Acromegaly, endoscopic transsphenoidal surgery, growth hormone, insulin-like growth factor-1

Introduction

Acromegaly is a chronic systemic disease characterized by excessive secretion of growth hormone (GH) and insulin-like growth factor 1 (IGF-1). Majority of cases are due to a GH-secreting pituitary adenoma.[1] The disease has an annual incidence of 3 per million and a prevalence of 60 per million globally. In India, the incidence rate is 0.49 per lakh person-years.[2]

Key clinical features of acromegaly include acral enlargement, headaches, visual disturbances, coarse facies, arthropathy, hyperglycaemia, cardiomyopathy and sleep apnoea. Patients with acromegaly have a 2–2.5 times higher mortality rate compared to the general population, largely due to cardiovascular risks such as dyslipidaemia, hypertension (HTN) as well as diabetes mellitus (DM).[3] Without treatment, acromegaly can reduce life expectancy by 10 years compared to healthy individuals.[4]

Transsphenoidal surgery (TSS) is the preferred treatment for acromegaly. The endoscopic approach is favoured because of its wide-angled panoramic view facilitating access to para and suprasellar lesions.[5] Radiotherapy and medications are often required in addition to surgery or, as standalone treatment when surgery is contraindicated, or declined.

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Various guidelines have previously been published to define remission criteria for acromegaly patients.[3,6,7] In 2022, the 14th Acromegaly Consensus Conference was held in Italy, to update the consensus guidelines on defining biochemical criteria for diagnosis and evaluating therapeutic efficacy which were published in 2023.[8]

We aimed to analyse the clinical characteristics and endocrinological outcomes, of patients with acromegaly who underwent endoscopic TSS at our hospital. Additionally, we assessed predictors of remission and remission rate according to the 2023 guidelines.

Materials and Methods

We conducted a hospital based, retrospective study of treatment naïve patients with acromegaly who underwent endoscopic TSS, between January 2020 and June 2024. Inclusion criteria included clinical signs and symptoms of acromegaly and IGF-I >1.3 times the upper limit of normal for age, with or without non-suppressed post glucose growth hormone (PGGH) levels. We excluded cases with incomplete or insufficient data as well as those who received prior medical/surgical therapy.

Clinical and hormonal profiles, comorbidities, imaging results, treatment modalities and outcome data were recorded. The duration of onset was estimated as the time interval between the clinical onset of disease and the time of diagnosis. The duration of follow-up was defined as the time between the first and last GH/IGF-I status assessment.

Laboratory measurements

IGF-1 levels were measured using immunochemiluminescent assay on IMMULITE 1000 systems (Siemens; intraassay variability of 2%–5%, interassay variability of 3%–7%). GH was determined using an electrochemiluminescent immunoassay (ECLIA; Roche Cobas E601, USA, intraassay coefficients of variation [CVs] 2.8%, interassay CVs 4.4%). GH assay was standardized according to the WHO standard 98/574, and IGF-1 assay followed the WHO standard 02/254.

PGGH test was performed using 75 g anhydrous glucose administered after fasting, and GH nadir assessed after 60 min. According to the 14th Acromegaly Consensus Conference, body mass index (BMI) based GH nadir cutoffs considered for diagnosis were >0.4 µg/L for BMI <25 kg/m^2 and >0.2 µg/L for BMI ≥25 kg/m^2.[8]

Serum cortisol, free thyroxine (FT4), thyroid stimulating hormone (TSH) and prolactin (PRL) were measured by a chemiluminescent immunoassay on Vitros 5600 system. Follicle stimulating hormone (FSH), luteinizing hormone (LH) and testosterone (T) were measured by enzyme-linked fluorescence assay (ELFA) (VIDAS). A morning cortisol <5 mcg/dl was considered indicative of hypocortisolism and was replaced. Secondary hypothyroidism was defined as a low fT4 with an inappropriately normal/low TSH. Serum T was measured in male patients before surgery and during follow-up. Secondary hypogonadism was defined as low T (<1.5 ng/ml) in males or as amenorrhea in females, both accompanied by inappropriately low FSH and LH levels. Random GH values measured on the post-operative day 2 were recorded. During hospitalization, patients were monitored for post-operative complications, including diabetes insipidus (DI), cerebrospinal fluid (CSF) rhinorrhoea, meningitis and other potential issues.

All available pre- and post-treatment gadolinium-enhanced magnetic resonance imaging (MRI) scans of the hypothalamo-pituitary area were reviewed. Imaging data were analysed to assess tumour volume and invasion. Tumours were categorized as either microadenomas (<1 cm) or macroadenomas (>1 cm) and evaluated for evidence of cavernous sinus invasion according to the Knosp classification, based on coronal T1-weighted contrasted imaging.

Patients' residual pituitary function was re-evaluated at their initial 6-week follow-up. They were instructed to withhold corticosteroid replacement 1 day before this assessment.

MRI scans conducted 12 weeks post-surgery were documented. Patients were considered in biochemical remission if their IGF-I levels at 12 weeks post-surgery were normalized for their age.

Statistical analysis

The statistical analysis was performed using SPSS software (version 29.0.2.0 (20). Data were presented as mean and range for continuous variables and as frequency for categorical variables. Clinical variables were compared using Chi-square/Fishers exact test. Receiver operating characteristic curve was used to assess the diagnostic ability of various clinical variables for remission. Univariate and multivariable logistic regression analysis were performed to identify the significant factors associated with remission and odds ratio was reported. P <0.05 (two-tailed) was considered statistically significant.

Ethical aspects

This retrospective study was approved by the ethical committee of Mahatma Gandhi Medical college and Hospital, MGUMST, Jaipur on 26/04/2024, vide letter number 2024/1905. Written informed consent was obtained from all patients in the study and use of the patient data for research and educational purposes. The procedures in the study follow the guidelines laid down in the Declaration of Helsinki 1964 and as revised later.

Results

Study population

Of the 42 patients, 17 were women and 25 were men, with a mean age of 36.43 ± 10.70 years (range 19-58 years). The average BMI was 26.29 kg/m^2. Gigantism, defined as height >97th percentile for age, was present in three patients. The average lag period from the onset of symptoms to diagnosis was 63.6 ± 45.6 months. The mean follow-up duration was 27.6 ± 24.6 months (range 4.8–72 months).

Clinical presentation[Figure 1]

Coarse facies (95.23%) and acral enlargement (97.6%) were the most frequent characteristics observed in our

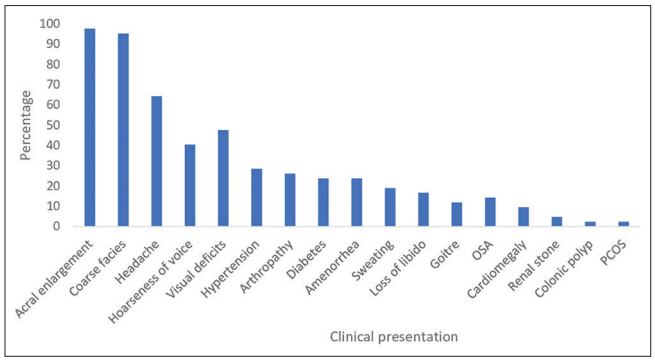

Figure 1: Bar diagram showing frequency of various clinical presentation

patients. The two most frequent presenting symptoms were headache (64.28%) and visual deficits (47.61%). Approximately one-fourth of the patients experienced musculoskeletal problems (26.19%). Increased sweating and goitre were present in 19% and 11.9% of patients, respectively. Amenorrhea affected nearly half of the females. Common comorbidities included DM (23.8%) and HTN (28.57%), followed by obstructive sleep apnoea (OSA) (14.28%). Cardiomegaly was observed in 9.53% of patients (4 cases), with no evidence of valvular dysfunction among them.

Four patients had genetically proven multiple endocrine neoplasia-1 syndrome. All exhibited primary hyperparathyroidism, and one patient also had a gastrinoma. Additionally, one patient with toxic multinodular goitre elected to undergo definitive surgery and was found to have papillary thyroid carcinoma on histopathology. Genetic testing in this case did not identify any mutation.

Pre-treatment hormonal profile

The mean pre-operative IGF-I was 730 ± 200 ng/ml (range 411–1282 ng/ml), and the mean pre-operative random GH was 35.25 ± 25.64 ng/ml (range 5.9–200 ng/ml). The average nadir GH level was 18.13 ± 22.35 ng/ml (range 2.2–131 ng/ml). No discordance was observed between nadir GH levels and IGF-1 levels in diagnosis of acromegaly.

The pre-operative hormonal suggested secondary hypogonadism in 41.66%, followed by secondary hypothyroidism (23.81%) and secondary cortisol deficiency (21.43%) [Table 1]. A total of 32 patients (74.4%) had at least one anterior pituitary function deficit.

Imaging features

Macroadenomas were more common than microadenomas (37 vs. 5, respectively). The mean maximum tumour diameter was 25.52 ± 10.52 mm (range: 6–54 mm). Invasive tumours were found in 23 patients, accounting for 54.8% of the cases.

Treatment modalities

All patients underwent endoscopic TSS. Among those with persistent disease and residual adenoma, four patients underwent a second TSS. During follow-up, 11 patients received fractionated radiotherapy, and 1 patient underwent gamma knife radiosurgery. All patients awaiting remission post-radiotherapy were offered monthly Octreotide depot therapy (somatostatin receptor ligand); however, only five opted for this treatment. Additionally, 15 patients were started on cabergoline during the follow-up period.

Table 1: Endocrine outcomes

Abnormality	Total pre-operative cases (%)	Total post-operative cases (%)	Recovered cases (%)[b]
Hypocortisolism	9/42 (21.43)	15/42 (35.71)	2/9 (22.22)
Hypothyroidism	10/42 (23.81)	13/42 (30.95)	2/10 (20.00)
Hypogonadism	15/36 (41.67)	16/36 (44.44)	6/15 (40.00)
Male, *n*=25	9/25 (36.00)	12/25 (48.00)	3/9 (33.34)
Female, *n*=11[a]	6/11 (54.54)	4/11 (36.36)	3/6 (50.00)

[a]Six women were excluded secondary to use of oral contraceptives, hysterectomy or menopause, [b]Percentage has been calculated for recovered cases using the total cases of individual hormone parameters in the pretreatment period as denominator

Complications

The commonest complication in the post-operative period was DI, occurring in nine patients (21.42%) patients and persisted beyond 6 weeks in two patients (4.76%). An altered sense of smell was reported in six patients (14.28%); all these patients experienced resolution by the first follow-up. No cases of meningitis, CSF leaks or other serious adverse outcomes were detected during the hospital stay.

Posttreatment hormone profile [Table 1]

At the 6-week follow-up, 35 patients (83.33%) had one or more hormonal deficiencies. Hypogonadism continued to be the most common pituitary hormone deficiency after surgery. New onset hypogonadism occurred in 28.6% of male patients (4 of 14). However, 33.34% of male patients with pre-operative hypogonadism (three of nine patients) experienced normalization of their testosterone levels after surgery. Among the 11 women younger than 50 yr who had not experienced menopause or hysterectomy, 6 (54.54%) were amenorrhoeic before surgery. Of these, three women (50%) regained regular menses after surgery. Of the 33 patients who were not on corticosteroids preoperatively, 12 patients (36.36%) were discharged on hydrocortisone; however, only 8 (24.24%) required steroid replacement beyond 3 months.

Outcome

Biochemical remission was achieved in 18 out of 42 patients (42.85%), including in all five patients with microadenomas and 35.13% of those with macroadenomas. Remission was determined based on IGF-I levels.

Clinical and laboratory improvement at the last follow-up period were analysed, showing soft tissue improvement of 47.61% and visual field recovery of 65% (13/20). Remission of HTN and diabetes mellitus was 16.66% (2/12) and 40% (4/10), respectively.

Table 2 compares patients with and without remission. Age, sex and BMI were not found to be predictive of remission ($P = 0.591$, $P = 0.414$ and $P = 0.376$, respectively). Tumours larger than 18.5 mm had a significantly lower rate of remission compared with smaller tumours ($P = 0.004$). Knosp grade 0–2 tumours were associated with significantly higher rates of remission compared with Knosp grade 3–4 tumours (72.2% vs. 27.8%, $P = 0.002$). Pre-operative PGGH levels ≤11.35 ng/ml and post-operative (day 2) GH levels ≤2.75 ng/ml were significantly associated with remission ($P = 0.002$ and $P < 0.001$, respectively) at 12 weeks. The mean pre-operative IGF-1 levels were not significantly different between the remission and non-remission groups (676.72 ng/ml vs. 771.54 ng/ml, $P = 0.131$).

The diagnostic ability of various clinical variables for predicting remission was evaluated [Figure 2]. Post-operative GH levels on day 2 demonstrated the highest diagnostic accuracy, with an area under the curve of 0.955 (95% confidence interval [CI]: 0.900, 1.000; $P < 0.001$). The cutoff value was 2.75 ng/ml with both sensitivity and specificity of 88.90% and 91.70%, respectively.

Logistic regression analysis identified several parameters significantly associated with remission, as shown in Table 3. Post-operative GH levels on day 2 (≤2.75 ng/ml) emerged as the strongest predictor of remission, with a crude odds ratio of 88.00 (95% CI: 11.18–692.55; $P < 0.001$) and an adjusted odds ratio of 63.90 (95% CI: 5.52–739.7; $P = 0.001$). Although Knosp grade, maximum tumour diameter and pre-operative PGGH levels showed significant associations in crude analyses, they lost significance after adjustment. On multivariate analysis, the only variable that remained predictive of remission was post-operative GH levels on day 2.

Discussion [Table 4]

This series evaluates the clinical presentations and outcomes of acromegalic patients at a single tertiary centre in western India, using the 2023 diagnostic and remission criteria. To

Table 2: Comparison of the characteristics of the patients with remission and no remission

Characteristics	Total cases ($n=42$), n (%)	Remission, n (%)		P
		Yes ($n=18$)	No ($n=24$)	
Age (years)				
≤35	23 (45.2)	9 (50.0)	14 (58.3)	0.591
>35	19 (54.8)	9 (50.0)	10 (41.7)	
Gender				
Male	25 (59.5)	12 (66.7)	13 (54.2)	0.414
Female	17 (40.5)	6 (33.3)	11 (45.8)	
Tumour size (mm)				
≤18.5	11 (26.2)	9 (50.0)	2 (8.3)	0.004
>18.5	31 (73.8)	9 (50.0)	22 (91.7)	
Knosp grade				
0–2	19 (45.2)	13 (72.2)	6 (25.0)	0.002
3–4	23 (54.8)	5 (27.8)	18 (75.0)	
Pre-operative IGF-1				
<800	28 (66.67)	16 (88.89)	12 (50)	0.114
>800	14 (33.33)	2 (11.11)	12 (50)	
Pre-operative PGGH (ng/ml)				
≤11.35	21 (50.0)	14 (77.8)	7 (29.2)	0.002
>11.35	21 (50.0)	4 (22.2)	17 (70.8)	
Post-operative GH Day 2 (ng/ml)				
≤2.75	18 (42.9)	16 (88.9)	2 (8.3)	<0.001
>2.75	24 (57.1)	2 (11.1)	22 (91.7)	

GH=Growth hormone, PGGH=Post glucose growth hormone, IGF-1=Insulin-like growth factor 1

Table 3: Logistic regression analysis of clinical parameters predicting remission in patients

Parameters	Univariate analysis		Multivariate analysis	
	P	Crude OR (95% CI)	P	Adjusted OR (95% AOR)
Knosp grade (3–4)	0.004	0.13 (0.03–0.51)	0.582	0.52 (0.05–5.38)
Maximum tumour diameter (≤18.50 mm)	0.006	11.00 (1.98–61.26)	0.647	1.95 (0.11–33.96)
Pre-operative PGGH (≤11.35)	0.003	8.50 (2.06–35.08)	0.128	6.73 (0.58–78.56)
Post-operative GH day 2 (≤2.75)	<0.001	88.00 (11.18–692.55)	0.001	63.90 (5.52–739.7)

OR=Odds ratio, CI=Confidence interval, GH=Growth hormone, PGGH=Post glucose growth hormone, AOR=Adjusted odds ratio

our knowledge, no prior studies on acromegaly have assessed patient outcomes based on the 2023 criteria.

Acromegaly is usually diagnosed in the fourth decade of life.[2] Our findings align with this, as the mean age at diagnosis was 36.43 years, with most patients between 30 and 50 years old at diagnosis. Approximately 95.0% of our patients exhibited acral enlargement and coarse facial features, consistent with previous studies that reported such changes in 90%–98% of patients.[2,9-11] Headache and visual deficits were the next common presentations, like the findings in the study conducted by Dutta *et al*.[9]

The prevalence of HTN (28.57%) and DM (23.8%) in our cohort was comparable to previous studies, where prevalence ranged from 18% to 60% for HTN and 16.23% to 52.5% for DM.[9,12-14] Arthropathy was less prevalent in our study than the previously mentioned figure of upto 60%–70%, possibly due to shorter lag period in our cohort.[15] OSA was diagnosed in six patients (14.28%). This comorbidity is currently under-assessed with prevalence reported to be between 19% and 79%, and a rising trend noted from the 1980s to 1990s, likely due to the increased use of polysomnography for diagnosis.[16] We did clinical assessment of OSA using Epworth Sleepiness Scale to diagnose OSA.

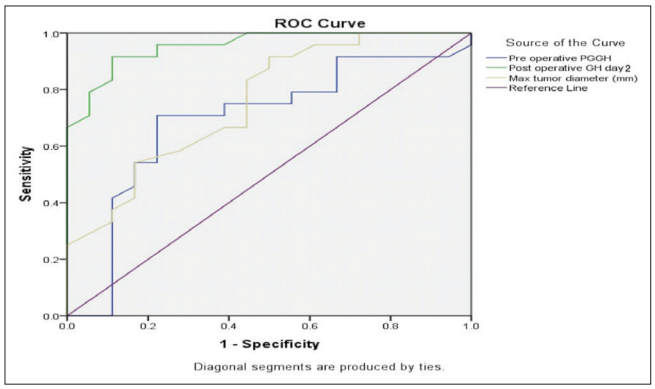

Figure 2: Receiver operating characteristic analysis of the various characteristics in predicting patients with remission

Preoperatively, 74.4% of patients had one or more anterior pituitary hormone deficiencies, and this figure increased to 83.33% in the post-treatment period, consistent with previous Indian studies.[2,9] These percentages were higher as compared to acromegaly series from Belgium, Spain and Germany.[17-19] Hypogonadism was the most common hormone deficiency in our series, like findings reported by Wani *et al*.[2] Post-surgery, 40% of patients with hypogonadism experienced recovery, compared to 50% reversibility noted in study by Katznelson *et al*.[20]

As per the recent consensus criteria, 42.85% of patients achieved biochemical remission (100% with microadenoma and 35.13% with macroadenoma). The treatment outcomes in our study could not be directly compared with previous studies because of the different remission criteria used. Prior studies from the Indian subcontinent, which applied the 2010 and 2014 consensus guidelines, reported overall remission rates of 23.7%–33.9%.[2,9,21] The better remission rate in our study could be attributed to the expertise of dedicated pituitary surgeons performing the surgeries using endoscopic approach. In Western literature, remission rates for microadenomas range from 67% to 100% and for macroadenoma, from 55% to 80%.[22-24]

Several studies have investigated factors influencing the treatment outcome in patients with acromegaly, with many reporting lower remission rates for larger and more invasive tumours.[22,24,25] Conversely, some studies have observed that tumour size may not be an independent predictor of remission.[25,26] In a study by Jane Jr *et al*., pre-operative IGF-I levels and random pre-operative GH levels emerged as significant independent predictors of outcome.[27] Additionally, post-operative GH concentrations have been identified as significant predictor of biochemical remission in some studies.[28,29] In our series, Knosp grade, maximum tumour diameter and pre-operative nadir GH were associated with remission but did not remain significant predictors in multivariate analysis. A post-operative day 2 GH level of less than 2.75 ng/ml provided the most accurate prediction of

Table 4: Comparison among different acromegaly series.

	Our study	Wani *et al*.[2]	Dutta *et al*.[9]	Sarkar *et al*.[21]	Jane Jr *et al*.[27]
Number of patients	42	51	271	113	60
Consensus criteria followed	2023 guidelines	2010 guidelines	2014 guidelines	2010 guidelines	2010 guidelines
Diabetes mellitus prevalence	23.8	21.6	16.23	29.2	-
Hypertension prevalence	28.57	45.1	17.7	37.1	-
Most common hormone deficiency	Hypogonadism (41.66%)	Hypogonadism (65%)	Hypothyroidism (55.5%)	Hypocortisolism (24.4%)	Hypogonadism (51.11%)
Treatment modalities	Endoscopic TSS	TSS	TNTS + Subfrontal	Endoscopic + microscopic TSS	Endoscopic TSS
Remission (overall)	40.47%	23.7%	28.5%	31.9	69.7
Microadenoma	100%	40%	38.8%		100
Macroadenoma	35.13%	19.5%	18.6%		60.9
Predictors of remission	Post-operative growth hormone	Adequacy of surgery	Adequacy of surgery	Pre-operative GH (<40 ng/ml) Adenoma size (<20 mm) Non-invasiveness	Knosp score, IGF-I, pre-operative GH levels, post-operative GH <2.5

PGGH=Post glucose growth hormone, IGF-1=Insulin-like growth factor 1, TSS=Transsphenoidal surgery, TNTS=Trans nasal trans sphenoidal

remission, highlighting its critical role in assessing successful outcomes in patients with acromegaly.

The limitations of our study include its retrospective design, relatively small sample size and short follow-up period. Furthermore, our study lacks detailed radiological and histological data, such as T2-signal intensity, granulation pattern, prolactin expression and Ki-67 index. These constraints, however, underscore the practical challenges encountered in routine clinical practice. Additionally, post-operative evaluations of certain comorbidities, such as cardiomyopathy and OSA, were not comprehensively conducted.

Conclusions

This study presents a comprehensive review of the clinical presentations and outcomes of acromegaly patients treated with endoscopic TSS at a referral centre in western India by endoscopic TSS, assessed according to the latest acromegaly consensus guidelines. Importantly, a post-operative day 2 GH level emerged as a significant predictor of patient outcomes. Our findings may augment patient counselling regarding early prognostic expectation and facilitate individualized post-operative management. The results highlight the need for collaborative efforts of the pituitary care team, suggesting potential areas for refinement in surgical procedures to remove larger tumours, leading to further improvement in remission rates. Larger prospective studies are needed to analyse the correlation between radiological and histological data and the rate of remission after surgery.

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Authors contribution

The concept of the study was given by Dr Rajeev Kasliwal and Dr S.K. Sharma. The designing was performed by Dr Jyoti Sharma and Dr Rajeev Kasliwal. Data of the study was acquired by Dr Jyoti Sharma, Dr Vineet Mishra, Dr B.S. Sharma, Dr Pankaj Gupta, Dr Puneet Shivnani, Dr Utkarsh Balani and Dr Payal Bargujar. The data was analysed by Dr Rajeev Kasliwal, Dr S.K. Sharma, Dr Jyoti Sharma and Dr Puneet Shivnani. Manuscript was prepared and edited by DR Jyoti Sharma, Dr Rajeev Kasliwal and Dr S.K. Sharma. Statistical analysis was performed by Dr Akash Mishra. Definition of intellectual content was given by Dr BS Sharma, Dr Pankaj Gupta and Dr S K Sharma. Manuscript review guarantor were Dr Rajeev Kasliwal and Dr S.K. Sharma.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence

No artificial intelligence (AI) tools were used in the development or preparation of this manuscript.

Data availability statement

In accordance with the journal's guidelines, we are committed to transparency and reproducibility in research. The data supporting the results of this study will be made available by the corresponding author upon reasonable request.

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