Non-specific Chief Complaints Among Oral Submucous Fibrosis Patients at Outpatient Department and Pan Shop at Rural Region in India

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Aim: The first communication with a healthcare professional is critical for determining the correct diagnosis, particularly when it comes to patients’ description of symptoms. This study aimed at exploring the primary symptoms observed in oral submucous fibrosis patients with non-specific complaints visiting outpatient department and pan shop at Kanpur, India.

Materials and Methods: It was a cross-sectional study involving a two-stage sampling to select clinically diagnosed oral submucous fibrosis (OSF) patients from the outpatient department and pan shop customers (PSCs) at rural healthcare centers. A total of 321 participants were selected based on convenience sampling. Patient demographics, history of relevant habits with a period, and socioeconomic status were all documented. The extent of mouth opening was used to grade OSF cases. Data were analyzed using MedCalc Version 19.7.2 with \( \chi^2 \), Wilcoxon signed-rank, and \( t \)-tests used, as appropriate, to calculate \( P \)-values.

Results: Out of the 184 OSF-OPD patients, only 59 (32.06%) described relevant disease symptoms of OSF: in stage III, 28.5% or stage IV, 38.7%. One hundred and twenty-five patients (67.93%) reported chief complaints (CCs) unrelated to OSF, and all of these cases were diagnosed with an early stage of OSF (stage I: 72.41% and stage II: 61.53%). Out of the total 137 PSCs, 74 PSCs have had prior dental consultations, but only 44 (32.11%) people had sought medical help because of OSF-related CCs.

Conclusion: A limited number of studies were conducted in this area, particularly in the rural population of central India. Our study found that considerable amount of main complaints from OSF patients was unrelated to their symptoms. There is insufficient knowledge of OSF symptoms among rural population, which further restricts early detection of the disease.

Keywords: Awareness, community, malignancy, oral disease, oral submucous fibrosis

INTRODUCTION

Oral submucous fibrosis (OSF) is a persistent, progressive condition distinguished by fibrosis of the oral cavity’s connective tissue stroma. OSF is induced by the practice of chewing areca nut/areca nut quid, which is very popular in Asian countries such as India.[1] In India, the prevalence of OSF spans from 0.62% to 6.42%.[2,3] One latest evidence with a broad cohort of 99 OSF cases found a 3.72% malignant transformation rate, with an estimated average of 37.42 months.[4] Furthermore, OSF has been associated with a reduced quality of life (QoL), with a substantial increase in effects as the disease progresses.[5,7] Because

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How to cite this article: Sachdev R, Garg K, Shwetam S, Srivastava A. Non-specific chief complaints among oral submucous fibrosis patients at outpatient department and pan shop at rural region in India. Int Soc Prev Communit Dent 2021;11:382-8.
of its significant risk of malignant transformation, OSF is considered a disease with a high mortality rate. Oral cancer is one of the widely prevalent cancer types emerging as a growing problem in various regions of the world, and it is the most common type of cancer in South Asian countries like India. Squamous cell carcinomas are the most prevalent form of oral malignancies. Thus, early detection of OSF-associated oral squamous cell carcinoma (OSCC) is the key to better patient prognosis.

Restricting diagnostic difficulties to early detection is the core component of enhancing OSF patients’ quality of life and survival by lowering their risk of oral tumor development. A comprehensive clinical analysis is required for early detection of OSF and OSCC from OSF, which is the absolute key to a good treatment plan. Routine monitoring is also recommended, and OSF patients should be closely supervised. The patient’s visit to a specialized/specialist healthcare provider, in contrast, becomes a dependent parameter for recognizing the condition and subsequent follow-ups. Besides, we also speculated that there could be a significant number of OSF patients in the population who have never visited a dental healthcare facility in rural communities, regardless of their knowledge of the OSF and its consequences. The objective of this research was to see how much people knew about OSF and its consequences. The next most anticipated method to find OSF individuals (second stage sample) in the general community is in nearby pan shops (khaini/gutkha, mawa, pan masala, tobacco, etc., selling place). After the five rural pan shop (PS) vendors (Shivrajpur 3 and Chaubepur 2) from Kanpur district, Uttar Pradesh, were selected, the respondents were recruited by using the convenience sampling method for detailed physical evaluation at the pan shop itself, the incisal opening of the mouth of each participant was assessed using the Vernier digital caliper, and patients were graded to stage I to stage IV OSF as described by Lai et al. Participants with OSF who visited these stores were personally interviewed after taking written content for examination by one individual in once-a-week dental checkup camp at pan shop. All participants were asked about dental visits to any specialist healthcare professional and the reason for the visit. Besides, data on age, sex, occupation, education, household monthly income, relevant habits, and mouth-opening measurements were also obtained. All oral examinations and interviews of total 137 individuals were performed at the site of PS in the dental camps.

MATERIALS AND METHODS

The research was conducted in a private tertiary dental health services facility at rural Kanpur (Uttar Pradesh, India). A two-stage random sampling method was used. The first sampling stage enrolled 184 clinically diagnosed OSF patients from the outpatient department and the second stage enrolled 137 from local pan shops from September 2020 to January 2021. Every participant submitted a written informed consent document. The Kanpur-based Private Dental College and Hospital’s Institutional Ethical Committee gave their approval number (RDC/RC/21). Patients with OSF (outdoor patient department (OPD)) were identified by a convenience sampling method, and during screening processes participants were encouraged to participate in the study based on the clinical criteria listed subsequently: intolerance to hot and spicy foods, pale oral mucosa, palpable fibrotic bands, and chronic, progressive trismus are all indications to check out for.

Demographic information as well as the history of relevant tobacco-chewing habits, with personal data on duration, has been recorded among the age group of 25–65 years. An updated Kuppuswamy’s socioeconomic status (SES) scale was used to assess each participant’s SES. This index is based on a composite score that takes into consideration the head of family’s education and occupation, as well as family’s monthly income, and assigns a score between 3 and 29. The research populations are divided into three groups based on their SES: higher (I), middle (II, III), and lower (IV) (IV, V). Each participant’s CC was registered and divided into two categories: (a) OSF-related complaints and (b) non-OSF-related complaints. OSF-related CCs included reduced mouth opening, burning sensation, and vesicle or ulcer formation (all in the context of reduced mouth opening).

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STATISTICAL ANALYSIS

Data were analyzed using MedCalc Version 19.7.2 (MedCalc Software Ltd, 64-bits, version 2020, Ostend, Belgium). Mean and SD were calculated, and χ² test, Wilcoxon signed-rank test, and t-test were used, as appropriate, to calculate P-values. The level of statistical significance was P < 0.05.
**Results**

**Sociodemographic characteristics (OSF-OPD patients)**

In the present study, a total of 321 participants were enrolled. The participant's age ranged from 25 to 65 years, with a mean of 40.2 (±4.6) years. A male majority was observed with a male: female ratio of 4.25:1 among OSF-OPD patients [Table 1]. Out of the 184 patients, 83 (45.1%) patients with OSF had a habit of khaini (areca nut quid) consuming, 67 (36.4%) chewed areca nut with khaini, while 34 (18.4%) had a habit of eating areca nuts only. The mean duration and frequency of these habits were 11.6 (±6.3) years and 12 (±3.8) times per day, respectively [Table 2]. Khaini was kept in the oral cavity, mainly in the lower buccal vestibule, for 5–25 min, whereas the areca nut was chewed for 3–15 min. The majority of OSF patients (32.27%) visiting an OPD had grade I disease, followed by grade III (30.4%), grade II (21.19%), and grade IV (16.8%). A majority of the OSF patients had a lower SES (76; 41.30%), followed by upper SES (61; 33.15%) [Table 2].

**CC analysis of OSF-OPD patients**

In the present study, 67.93% of the OSF-OPD patients showed CCs that were not related to OSF, and only 59 (32.06%) patients described OSF-related CCs. A significantly higher number of OSF patients with grade IV disease (12; 38.70%) reported OSF-related CCs compared with others in the grade I disease group (16; 27.5%) [P < 0.001; Table 3]. Among 184 OSF patients, the most commonly described CC was depletion in the mouth opening (12; 6.52%), followed by a sudden difficulty in opening the mouth due to pain in the third molar region (7; 3.80%), whereas non-healing oral ulcers (4; 2.17%) and pain in the pre-auricular region (2; 1.08%) were the least common CCs. Among, non-OSF-related CCs, pericoronitis (52; 28.26%) was the most common cause, followed by toothache (15; 8.15%) and tooth pigmentation (14; 7.60%). There were a few other non-OSF-related CCs including mobility of teeth (7; 3.80%), gingivitis (8; 4.34%), tooth sensitivity (6; 3.26%), and traumatic ulcers (9; 4.89%) [Table 4].

Regarding SES, a significantly higher number of OSF patients with a lower SES reported OSF-related CCs (29; 38.15%). The other group of participants with middle and lower SES reported non-OSF-related CCs [(31; 65.95%) and (47; 61.8%)] [Table 5].

**Analysis of CC made by PSC patients**

Males made up the entire group of 137 people who took part in the study at PSs. In most rural areas of India, women do not visit PSs due to social norms. The ages of PSCs ranged from 25 to 65 years, with a mean of 47.5 (±4.1) years. A majority of the individuals had stage III disease (52; 37.9%) OSF, followed by stage IV (35; 25.5%), stage II (34; 24.8%), and stage I (16; 11.6%). Out of the 137 individuals, 63 (45.98%) had not visited a dental healthcare professional in their lifetime [Table 2]. Seventy-four individuals with a prior dental consultation had made visits for non-OSF-related CCs, including stains on teeth (15.32%), toothache (8.75%), and pain in the third molar region (8.02%) [Table 6]. About 85.40% of the OSF-PSCs were found with CCs that were not related to OSF, and only 20

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**Table 1: Profile characteristic of OSF-OPD patients and PSCs**

| Parameters | OSF-OPD* | PSC** |
|-----------|----------|-------|
| Number (n) | 184 | 137 |
| Age (years) | 25–35 28.3±4.2 29.4±3.7 |
| | 35–45 37.2±2.3 42.6±6.8 |
| | 45–55 49.7±6.3 52.1±4.3 |
| | 55–65 61.8±5.7 57.4±3.8 |
| Mean age (SD***) | 25–65 40.2±4.6 47.5±4.1 |
| | | 61.8±5.7 57.4±3.8 |
| Sex | Male 149 (80.9%) 122 (89.05%) |
| | Female 35 (19.02%) 15 (10.94%) |

*OSF-OPD: oral submucous fibrosis patients from outdoor patient department, **PSC: customers at pan shop having oral submucous fibrosis

**Table 2: Demographic details of OSF-OPD patients and PSCs**

| Parameters | OSF-OPD* | PSC** |
|-----------|----------|-------|
| Socioeconomic position | Lower 76 (41.30%) 56 (40.87%) |
| | Middle 47 (25.5%) 34 (24.8%) |
| | Upper 61 (33.15%) 47 (34.30%) |
| Habit | Areca nuts 34 (18.4%) 27 (19.7%) |
| | Khaini/gutkha 83 (45.1%) 74 (54%) |
| | Areca nuts+khaini/gutkha 67 (36.4%) 36 (26.2%) |
| Duration of habit (in years) | 11.6 (±6.3) 7.8 (±7.7) |
| Frequency of habits (times per day) | 12±3.8 9.2±2.3 |
| Stages of OSF | Stage I 58 (31.5%) 16 (11.6%) |
| | Stage II 39 (21.9%) 34 (24.8%) |
| | Stage III 56 (30.4%) 52 (37.9%) |
| | Stage IV 31 (16.8%) 35 (25.5%) |
| Previous dental visit | Yes 56 (30.4%) 74 (54%) |

*OSF-OPD: oral submucous fibrosis patients from outdoor patient department; **PSC: customers at pan shop having oral submucous fibrosis
(14.59%) patients described OSF-related CCs. This study comprises that higher number of OSF patients with grade IV disease (22.8%) reported OSF-related CCs compared with others in the grade I disease group (12.5%), which was found to be insignificant [P < 0.0932; Table 7].

**Discussion**

Burning sensations, trismus, ulceration, and xerostomia are all signs of OSF, which has a direct impact on an individual's well-being. Patients with these premalignant disorders must visit dental care facility. In a study done by Gadbail et al., like almost a quarter of the patients (26.58%) had come for OSF-related symptoms, whereas the rest had come for problems unrelated to OSF, which was found to be similar to the current research.

We examined further into dental visit patterns of PSCs with OSF disorder in addition to the findings from the CC study of OSF-OPD patients. In their research, Gadbail et al. discovered that only 5 (4.80%) PSCs had already consulted dental healthcare professionals.

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**Table 3: Chief symptoms of OSF-OPD patients related to and unrelated to OSF**

| Stages of OSF | Total | χ² | Z-value | P-value |
|---------------|-------|----|---------|---------|
| Stage I | Stage II | Stage III | Stage IV | 184 | 119.04 | -2.0226 | <0.0001 |
| Related with OSF* | 58 | 39 | 56 | 31 | 184 | 59 (32.06%) | <0.0001 ** |
| Non-related with OSF | 16 (27.5%) | 15 (38.46%) | 16 (28.57%) | 12 (38.70%) | 59 (32.06%) | <0.0001 ** |

*OSF-OPD: oral submucous fibrosis patients from an outdoor patient department; ** statistically significant at P<0.05 χ² test; Wilcoxon signed-rank test*

**Table 4: Characteristic of CC and stages of OSF in OSF-OPD**

| Variables | Stage I | Stage II | Stage III | Stage IV | Total |
|-----------|---------|---------|-----------|---------|-------|
| Chief complaint (n) | 58 | 39 | 56 | 31 | 184 |
| Related with OSF* | 4 (6.89%) | 5 (12.82%) | 2 (3.57%) | 1 (3.22%) | 12 (6.52%) |
| Non-related with OSF | 14 (22.95%) | 16 (34.04%) | 29 (38.46%) | 12 (32.06%) | 59 (32.06%) |

*OSF-OPD: oral submucous fibrosis patients from an outdoor patient department*

**Table 5: Chief problems and social status in OSF-OPD patients with and without OSF**

| Variables | High (n) | Medium (n) | Low (n) | Total | χ²=225.02 |
|-----------|----------|-----------|--------|-------|-----------|
| Chief complaints | 61 | 47 | 76 | 184 | **P-value** |
| Related with OSF* | 14 (22.95%) | 16 (34.04%) | 29 (38.15%) | 59 (32.06%) | <0.0001 |
| Non-related with OSF | 47 (77.04%) | 31 (65.95%) | 47 (61.8%) | 125 (67.93%) | *Chi square* |

*OSF-OPD: oral submucous fibrosis patients from an outdoor patient department; ** statistically significant at P<0.05 χ² test; *Chi square*
for OSF-related symptoms, whereas there was no substantial correlation in the current study. These findings indicate that there could be a greater group of individuals with OSF in society who have never seen a dental hospital/healthcare provider for any OSF-related or non-OSF-related dental symptoms and therefore have never been considered.\[14\] Perhaps, this is due to the absence of awareness of the disease and limited knowledge of its serious potential for malignant transformation.\[16\]

Needless to say, there is scarce literature obtainable on OSF awareness and knowledge research in the rural region of central India. As a result, such research is urgently needed to determine the severity of the situation and deal with it accordingly. There is serious disagreement about OSCC early diagnosis methodologies until this scenario is resolved, as OSCC has a stronger prognosis when diagnosed early. The most common CC in OSF patients, according to Gadbail \textit{et al.},\[14\] was spontaneous discomfort opening the mouth due to impaction of the third mandibular molar and associated pericoronitis (48; 30.37%), which was also observed in the current research, and interestingly, this was also the most common symptom among non-OSF-related CCs. OSF was diagnosed in all of these patients and included clinical characteristics such as blanched buccal mucosa, atrophic uvula, a history of burning sensations, and gradually decreased mouth opening. OSF has been shown to aggravate pericoronitis in patients with impacted mandibular third molars in several studies. Because of their reduced capability to open their mouths, individuals with pericoronitis have a difficult task associated with their oral hygiene. As OSF is distinguished by a gradually reduced mouth opening, it exacerbates difficulties in opening the mouth, making oral hygiene maintenance more difficult in patients with pericoronitis.\[15\]

Moreover, in patients with OSF, the pericoronal flap over the last mandibular molar can be more firm and resilient, preventing adequate hygiene. Pericoronitis is associated with acute and extreme pain (unlike OSF, which is mostly associated with manageable symptoms), and several patients in the current study by Gadbail \textit{et al.}\[14\] documented pericoronitis associated with third mandibular molar impaction (40.66%), which was found similar to the present study. Therefore, it is essential to mention that OSF patients with pericoronitis have increased symptoms of both conditions, resulting in functional limitations, such as teeth brushing and chewing restrictions, further deteriorating the patients’ oral and general health. Regular dental and oral health checkups at dental clinics or hospitals are unusual in India’s rural population due to a lack of dental and oral health awareness. Individuals should not seek professional help

Table 6: Characteristic of CC and stages of OSF in PSCs

| Stages of OSF | Total |
|--------------|-------|
| Stage I      | 16    |
| Stage II     | 34    |
| Stage III    | 52    |
| Stage IV     | 35    |
| **Total**    | 137   |

| Chief complaints                      | Stage I | Stage II | Stage III | Stage IV | **Total** |
|---------------------------------------|---------|----------|-----------|----------|-----------|
| Related with OSF*                    | 16 (12.5%) | 34 (20.58%) | 52 (15.38%) | 35 (8.57%) | 137 (14.59%) |
| Progressive reduced mouth opening with burning sensation | 2 (12.5%) | 7 (20.58%) | 8 (15.38%) | 3 (8.57%) | 20 (14.59%) |
| Not related with OSF*                | 3 (18.75%) | 2 (5.88%) | 11 (21.15%) | 5 (14.28%) | 21 (15.32%) |
| Stains                               |         |          |           |          |           |
| Toothache                            | 5 (31.25%) | 2 (5.88%) | 3 (5.76%) | 2 (5.71%) | 12 (8.75%) |
| Pain in third molar                  | 1 (6.25%) | 1 (2.94%) | 4 (7.69%) | 5 (14.28%) | 11 (8.02%) |
| Other                                 | 1 (6.25%) | 5 (14.70%) | 2 (3.84%) | 2 (5.71%) | 10 (7.29%) |
| Not visited a dental service          | 4 (25%) | 17 (50%) | 24 (46.15%) | 18 (51.42%) | 63 (45.98%) |

*OSF: oral submucous fibrosis

Table 7: Chief problems in OSF-PSCs related to and unrelated to OSF

| Stages of OSF | Total | $\chi^2$ | Z-value | P-value** |
|---------------|-------|---------|---------|-----------|
| Stage I       | 16    | 34      | 52      | 35        | 137       |
| Stage II      | 2 (12.5%) | 7 (20.58%) | 8 (15.38%) | 3 (22.8%) | 20 (14.59%) |
| Stage III     | 14 (87.5%) | 27 (79.4%) | 44 (84.61%) | 32 (91.42%) | 117 (85.40%) |
| Stage IV      |       |         |         |           |           |

*OSF: oral submucous fibrosis, **P-value significant at <0.05

\textsuperscript{a}Chi square

\textsuperscript{b}Wilcoxon signed-rank test
through dental care facilities unless and until they have a significant impairment in physical functioning.\[14\]

The intense pain associated with dental caries and pulpitis was found to be the most common reason for the impairment of functional capacity in the current study, and so as an outcome, 20.68% of the participants in Gadbail et al.'s\[14\] study visited dental hospitals with a CC of toothache due to dental caries, with or without periapical inflammation.

The majority of the patients were in their second and third years as an adult. People in these age groups are typically more conscious of their social lives and risk factor for malignant transformations in OSF.\[17\] Oral ulcers caused by chronic trauma from buccally positioned third molars and sharp edges of attrited posterior teeth can be another trigger of malignant transformations in OSF.\[17\] OSF patients documented CCs such as tooth mobility (periodontitis) (6.03%), gingiva redness (4.31%), sensitivity (4.31%), and traumatic ulcers (4.31%) in a study conducted by Gadbail et al.,\[14\] and the findings were close to the current study. To reduce the risk of malignant transformation in OSF patients, the above-mentioned conditions must be managed and prevented.

Four cases of histopathologically well-differentiated squamous cell carcinomas and two cases of extreme epithelial dysplasia were included in this report. The results of this study back up evidence of a rising pattern of OSF-associated OSCC, as well as OSF’s growing malignant potential.\[17\] In their analysis, Gadbail et al.\[14\] found that four-stage I OSF patients (3.44%) had a CC of pain in the pre-auricular area (TMJ). Extreme tooth attrition can cause pain by reducing vertical occlusal height, causing forward movement of the mandible, and pulling on the TMJ ligaments. However, there is no evidence of a correlation between OSF and TMJ pain or myofacial pain dysfunction syndrome in the literature.

OSF was diagnosed as an incidental finding in 73.41% of patients with non-OSF-related CCs in a study conducted by Gadbail et al.\[14\] The fact that nearly two-thirds of the patients (69.55%) had early stage OSF (stage I (47.05%) and stage II (22.5%)) is remarkable. In the current study among patients who reported disease symptoms, two-thirds of the OSF patients had moderately advanced and advanced stages of the disease (stage III [20.58%] and stage IV [4.41%]). According to the reports in the literature, the degree of mouth opening has no connection to epithelial dysplasia or the malignant transformation of OSF (even early stage OSF can transform into OSCC).\[18\]

Although two-thirds of the patients in this study were found to have stage I and stage II OSF, these patients, like those in Gadbail et al.'s\[14\] study, can progress to OSCC. As a response, we assume that early detection strategies should be implemented during the initial diagnosis to reduce the burden of oral cancer and its subsequent complications. A significant number of OSF patients in the current study had a high SES. These findings contradict a recent study published in 2019 by Gondvikar et al.,\[19\] which suggested a higher prevalence of OSF, especially in advanced stages in patients with a low SES. Even though therapeutic options are available, the higher prevalence of OSF in lower SES groups may be due to their low purchasing power.\[20\]

Low academic levels and the type of job could also play a role in the development and progression of OSF. Although education has an impact on occupation, lower SES individuals have less academic credentials when combining non-professional occupations. In this study, a significantly higher number of OSF patients with middle and low SESs had non-OSF-related CCs in contrast to those with an upper SES. The result of the present study supports Gondvikar et al.’s\[19\] study investigation, which demonstrated a strong association between lack of awareness of OSF and SES. During their working hours, most of the lower SES individuals in central rural India (where the population of the study currently lives) consume khaini/gutkha and other items containing areca nuts. Also, the study population has restricted knowledge and awareness of OSF and its complications.

**Conclusion**

The findings of this study indicate that many patients with OSF visits are incidental, which accentuates lack of slight diligence of the rural population. The current study’s major feature is a clear representation of OSF patients’ dental visit patterns, which may affect the early detection and prevention of OSCC associated with OSF. Even so, regular dental and oral health checkups vary; long-term multicenter studies spanning several regions and provinces will provide a deeper understanding of such a scenario in central India’s rural areas. Large community awareness initiatives and the introduction of basic information about OSF and its potential malignancy risks through advertisements, awareness rallies, street theater, and social media knowledge in schools and villages are essential. The rural population is the most vulnerable group and is at higher risk of areca nut addiction than the urban population; therefore, media attention mostly on the
carcinogenic potential of areca nuts, similar to the advertising of tobacco products, should also be issued. There is also a need for thorough clinical examinations of all patients, despite their CCs, and it is necessary to preserve follow-up documents in all health facilities.

**Future scope**

Patients with OSF and OSF-PSCs visited dental hospitals with a variety of non-specific major complaints. Oral cancer early detection techniques can be hampered by a lack of knowledge of the disease. Large-scale public awareness programs and the introduction of basic knowledge of OSF and its fundamental design are crucial. The risks of malignancy through posters, awareness campaigns at school, company governance level, and rallies of awareness and advertisements in social media are at the community level.

**Acknowledgements**

Authors would like to acknowledge all the participants of the study.

**Financial support and sponsorship**

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

**Conflicts of interest**

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

**Authors contributions**

All authors had contributed to study conception, data collection, data acquisition and analysis, data interpretation, and manuscript writing. All authors have read and approved the manuscript.

**Ethical policy and institutional review board statement**

Ethical approval was obtained prior to the study process from Institutional Ethics Committee (protocol ref no. RDC/RC/21).

**Patient declaration of consent**

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their clinical information to be reported in the journal.

**Data availability statement**

The data set is available on request from corresponding author.

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