# Morphologic evaluation of the pre-lacrimal recess using computed tomography

# **Original Article**

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# Abstract

Objetives: This work aims to evaluate the morphology of the pre-lacrimal recess (PLR) of the maxillary sinus (MS) in the Portuguese population. Material e Methods: We performed a retrospective analysis of computed tomography images of the paranasal sinuses of 75 patients (150 sides). Multiple morphologic parameters of the MS and of the PLR were evaluated, such as the pneumatization of the MS, the width of the PLR, the thickness of the medial wall of the PLR and the angle of the piriform notch (APN). We also studied the relationship between the anterior superior alveolar nerve (ASAN) and the medial wall of the PLR.

Results: None of the analyzed hypoplasic MS (6/250) had PLR. PLR was present in 86,2% and 88,0% of the normal and hyperplasic MS, respectively.

The average width of the PLR was 4,90 +/- 1,69 mm. Its medial wall had an average thickness of 3,14 +/-1,86 mm. There was an inverse association between the width of the PLR and the thickness of its medial wall (p<0,001). There was also an association between the degree of pneumatization of the MS and the thickness of the medial wall of the PLR. In hyperplasic MS this wall was significantly thinner (p=0,009). The APN had a mean amplitude of 43,94 +/- 12,14°. The ASAN was in a vulnerable position in almost 40% of the cases.

Conclusion: The high variability of the anatomy of the PLR implies that a detailed morphologic evaluation of this region using CT scan in order to correctly select the patients that can benefit from a pre-lacrimal endoscopic approach.

Keywords: Otorhinolaryngology, endoscopic sinonasal surgery, maxillary sinus, pre-lacrimal recess

# Introduction

The maxillary sinus (MS) can be the site of inflammatory, infectious, and neoplastic disease<sup>1</sup>, and endoscopic sinus surgery have become the first-line treatment for most of these diseases in recent years<sup>2, 3</sup>. However, accessing certain regions of the MS, such as

the anterolateral wall and anterior portion of the floor<sup>1, 4</sup>, poses significant challenges with traditional endoscopic techniques.

Accessing these MS regions is particularly important in cases of benign sinonasal tumors, such as inverted papilloma, which grow in these areas. Successful treatment relies on the excision of the complete tumor, mucosa, and periosteum in and around the implantation area<sup>1, 5</sup>. Thus, external or more extensive endoscopic approaches have been used to overcome the difficulties in treating these lesions<sup>6-8</sup>. However, these approaches are often associated with high complication rates, including facial and dental paresthesia, persistent facial pain, epiphora, nasal crusting, and empty nose syndrome<sup>8-10</sup>.

Zhou et al.<sup>11</sup> described an endoscopic prelacrimal approach (EPLA) that can help to visualize and access the anterior region of the MS and preserve the inferior turbinate and the nasolacrimal canal (NLD). This minimally invasive technique has been proven to be effective in treating sinonasal tumors arising in the anterior MS region<sup>1,12</sup> and for successfully accessing the pterygopalatine and infratemporal fossae through the transmaxillary route <sup>4</sup>.

EPLA has been associated with low morbidity, as it has low risk of several complications associated with other surgical techniques. However, this procedure can result in anterior superior alveolar nerve (ASAN) injury, which can lead to paresthesia in its innervation territory<sup>1,13</sup>.

While EPLA offers distinct advantages, its feasibility relies on favorable anatomy of the prelacrimal region. Some studies have reported substantial anatomical variability of this region<sup>3,6</sup>; thus, preoperative evaluation of the paranasal sinuses by computed tomography (CT) is essential for accurate selection of the eligible patients.

This study aimed to examine the morphology of the prelacrimal recess (PLR) in the Portuguese population for the first time. The focus was on identifying key patient selection criteria and predicting potential complications of EPLA.

# Materials and methods

This retrospective study analyzed the CT images of the paranasal sinuses of 75 adult patients who underwent septoplasty at the Hospital Pedro Hispano in 2023. Patients with neoplastic sinonasal or extensive inflammatory pathology, prior endoscopic sinonasal surgery, or CT scans with artifacts were excluded from the study.

The images were obtained with a multidetector BrightSpeed 16 CT scanner<sup>®</sup> (General Electric Co.) and analyzed with the PACS Synapse<sup>®</sup> software version 7.2.000 (FUJIFILM Healthcare Americas Corporation).

The degree of MS p neumatization was assessed on all sides analyzed, according to the criteria described by Soyal et al<sup>6</sup>. The maximum vertical and transverse diameter of each orbit and MS were measured (Figure 1). Subsequently, the ratio between the maximum MS and maximum ipsilateral orbit diameters was calculated for each side (maximum MS diameter/maximum orbit diameter). A ratio< 0.5 was defined as a hypoplastic sinus;  $\geq$  0.5 and  $\leq$  1 as a normal sinus; and > 1 as a hyperplastic sinus.

All morphometric parameters of the PLR were analyzed in the axial plane corresponding to the insertion of the inferior turbinate into the frontal process of the maxilla (Figure 2).

The PLR was considered absent when the anterior NLD wall was adjacent to the posterior surface of the anterior MS wall (Figure 3A). If present, it was classified as anterior if a portion of the PLR extended anterior to the NLD, or lateral if the entire PLR was completely lateral to the NLD (Figures 3B and 3C).

A line was drawn parallel to the posterior surface of the anterior MS wall, and two additional lines were drawn parallel to it, one tangential to the anterior wall and the other tangential to the posterior NLD wall, and the distance between them was measured to determine the PLR (PLR<sub>width</sub>) and NLD (NLD<sub>width</sub>) width, respectively (Figure 4). According to the criteria proposed by Simmen et al., PLR was classified as type I if PLR<sub>width</sub> < 3 mm, type II if between 3–7 mm, and type 3 if > 7 mm.

#### Figure 1

Maximum vertical diameter of the right orbit (A) and right maxillary sinus (MS) (B) to assess the degree of pneumatization of the right MS.



#### Figure 2

Example of how the axial plane was selected to analyze the morphometric parameters of the prelacrimal recess (PLR).



The PLR medial wall thickness was also measured ( $PLR_{thick}$ ) (Figure 4).

The pyriform notch angle (PNA) was measured according to the method described by Arosio et al<sup>13</sup>. A line was drawn parallel to the posterior surface of the anterior MS wall (line A), another line was drawn parallel to the internal surface of the frontal process of the maxilla (line B), and the point of intersection between them was marked (point I). Subsequently, a third line tangential to the NLD and passing through point I (line C) was drawn. The amplitude of the PNA was measured between lines A and C (Figure 5).

The position of the ASAN was assessed by tracing its path from the infraorbital canal

#### Figure 3

(A) Nasolacrimal duct (NLD) adjacent to the anterior maxillary sinus (MS) wall with no prelacrimal recess (PLR). (B) and (C) PLR (\*) in the anterior and lateral location, respectively.



#### Figure 4

Example of the method used to measure the width of the prelacrimal recess (PLR) (red arrow) and nasolacrimal duct (green arrow) and thickness of the medial PLR wall (blue arrow).



to the frontal process of the maxilla. It was deemed to be in a vulnerable position if it was posterior to line A or medial to line B, which were previously defined (Figure 6).

All variables were measured three times to calculate their averages, which were used for statistical analysis.

The data were analyzed using SPSS software version 28 (SPSS Inc., Chicago IL., USA). The t-test for independent samples and one-way analysis of variation (ANOVA) were used to compare the averages. The Chi-Square test was used to analyze the association between categorical variables. Significance level was set at p = 0.05.

#### Figure 5

Method used to measure the amplitude of the pyriform notch angle (PNA).



# Results

This study analyzed CT scans of the paranasal sinuses of 75 patients (150 sides). Most patients were women (52%) with an average age of 38.49 (± 12.19) years.

In total, only 4% (6/150) of the MS were found to be hypoplastic. The most common pneumatization pattern was normal (62.7%), followed by hyperplastic (33.3%). On comparing the degree of MS pneumatization between the sexes, hyperplastic sinuses were found to be more prevalent in men (p = 0.001) (Table 1). The PLR was present on 125 out of the 150 sides analyzed, accounting for 83.3% of the cases. There were no significant differences in the presence of PLR between the sexes.

#### Figure 6

(A) Anterior superior alveolar nerve (ASAN) located posterior to line A, in a vulnerable position. (B) ASAN located anterior to line A and lateral to line B, in a non-vulnerable position.



None of the hypoplastic MS had a PLR, which had similar prevalence rates in normal and hyperplastic sinuses (86.2% and 88.0%, respectively) (Table 2).

Among the cases where the PLR was present, it was classified as anterior in 79.2% cases, with no significant differences between the sexes. However, a significant association was observed between PLR width and PLR location (p < 0.001), with 100% of type III, 85.1% of type II, and 25% of type I PLR being classified as anterior (Table 3). The average PLR width was 4.96 (± 1.69) mm, with no significant differences observed between the sexes or degrees of MS pneumatization. According to the classification proposed by Simmen et al., 12.8% of the PLRs were type I, 75.2% were type II, and 12.0% were type III (Table 1).

The medial PLR wall had an average thickness of 2.94 (± 1.67) mm. An association was found between the degree of MS pneumatization and PLR wall thickness. Notably, hyperplastic sinuses had a lower average PLR<sub>thick</sub> than normal sinuses (p = 0.009) (Table 2). PLR<sub>width</sub> was inversely related to PLR<sub>thick</sub>; thus, the greater the PLR<sub>width</sub>, the lower the PLR<sub>thick</sub> (p < 0.001) (Table 3). The average PNA amplitude was 43.94° (± 12.14), with no significant

differences between the sexes or degrees of MS pneumatization. However, there were significant differences between the average PNA amplitude of type I and type II PLR (p = 0.046) (Table 3).

Regarding the ASAN position, it was deemed vulnerable in 51 out of 125 cases (40.8%), with no ASAN position differences between the sexes, degrees of MS pneumatization, or PLR types. PNA amplitude and ASAN location also showed no significant association (p = 0.746).

#### Discussion

The pyramidal shape of the MS hinders endoscopic access to some of the walls and recesses<sup>1, 4</sup>. While this anatomy may not interfere with the successful treatment of some diseases, such as chronic rhinosinusitis where the primary objective is to restore ventilation and mucociliary clearance<sup>1</sup>, it can be problematic in conditions such as benign MS tumors, e.g., inverted papilloma. In such cases, incomplete resection of the sinus and mucoperiosteum around the implantation area is associated with a high risk of tumor recurrence<sup>5</sup>. Therefore, adequate visualization and access to the implantation area is essential for treating these tumors.

#### Table 1 Comparison of results by sex Women Men Total Variable (<u>39 participants)</u> (75 participants) (36 participants) (78 sides) (72 sides) (150 sides) MS pneumatization - Hypoplastic 1 (1.3) 5 (6.9) 6 (4.0) - Normal 59 (75,6) 35 (48,6) 94(62,7) - Hyperplastic 18 (23,1) 50 (33,3) 32 (44,4) Presence of PLR - Yes 67 (85,9) 58 (80,6) 125 (83,3) - No 11 (14,1) 14 (19,4) 25 (16,7) PLR location - Previous 56 (83,6) 43 (74,1) 99 (79,2) - Sideview 11 (16,4) 15 (26,9) 26 (20,8) PLR width 4,90 (1,69) - Average (SD) 4,96 (1,69) 4,79 (1,70) PLR width (type) 9 (13 4) 7 (12 1) 16 (12 8) - Type I (< 3 mm)

- Type II (3–7 mm) - Type III (> 7 mm)	49 (73,1) 9 (13,4)	45 (77,6) 6 (10,3)	94 (75,2) 15 (12,0)	0,829a
PLR wall thickness - Average (SD)	2,94 (1,67)	3,38 (2,05)	3,14 (1,86)	0,190b
<b>PNA</b> - Average (SD)	45,47 (13,6)	42,14 (9,98)	43,94 (12,14)	0,125b
NLD width - Average (SD)	9,08 (2,82)	9,88 (2,41)	9,47 (2,66)	0,066b
<b>Relationship with the ASAN</b> - Yes - No	27 (40,3) 40 (69,7)	24 (41,4) 34 (58,6)	51(40,8) 74 (59,2)	0,849a

PNA – pyriform notch angle, NLD – nasolacrimal duct, ASAN – anterior superior alveolar nerve, PLR – prelacrimal recess,

MS - maxillary sinus, SD - standard deviation. Significance level: p = 0.05. a - Chi-square test; b - T-test for independent samples.

More conservative endoscopic approaches, such as type 1<sup>8</sup> endoscopic medial maxillectomy, often do not provide adequate visualization of the anterior region of the anterolateral wall, floor, and medial wall of the MS. Although bent endoscopes allow visualization of these regions, they increase the surgical complexity and may require specific surgical instruments<sup>1, 4, 7</sup>.

To address these challenges, external or more extensive endoscopic approaches have been utilized. However, external approaches, including the Caldwell procedure, have a high complication rate of up to 75%, often resulting from injury to the infraorbital nerve and its branches<sup>9,15</sup>. More extensive endoscopic approaches (endoscopic medial maxillectomy  $\geq$  type 2<sup>8</sup>) are also associated with a higher incidence of postoperative complications, including the empty nose syndrome, nasal crust formation, and epiphora<sup>7, 8, 10</sup>.

p-value

0.001a

0,269a

0,263a

0,501b

Zhou et al.<sup>11</sup> described EPLA as a minimally invasive endoscopic approach for accessing the MS through the PLR It ensured better visualization and access to the anterolateral region and floor of the MS, while avoiding the complications associated with external approaches, such as type 1 endoscopic medial maxillectomy, mega antrostomy, and type 3 antrostomy proposed by Simmen<sup>8.</sup> The EPLA provides the same visibility as type 3 medial maxillectomy, but with a reduced risk of postoperative sequelae. Furthermore, its allows intra- or postoperative conversion

#### Table 2

Comparison of results by the degree of maxillary sinus pneumatization

Variable	Hypoplastic (6 sides)	Normal (94 sides)	Hyperplastic (50 sides)	p-value
Presence of PLR - Yes - No	0 (0,0) 6 (100,0)	81 (86,2) 13 (13,8)	44 (88,0) 6 (12,0)	< <b>0,001</b> a
PLR location - Previous - Sideview	-	61 (75,3) 20 (24,7)	38 (86,4) 6 (13,6)	0,146a
PLR width - Average (SD)	-	4,72 (1,77)	5,22 (1,50)	0,057b
PLR width (type) - Type I (< 3 mm) - Type II (3–7 mm) - Type III (> 7 mm)	- -	13 (16,0) 58 (71,6) 10 (12,3)	3 (5,8) 36 (81,8) 5 (11,4)	0,314a
PLR wall thickness - Average (SD)	-	3,43 (1,83)	2,54 (1,75)	<b>0,009</b> b
<b>PNA</b> - Average (SD)	-	44,14 (13,35)	42,14 (9,98)	0,944b
NLD width - Average (SD)	8,94 (0,85)	9,10 (2,51)	10,22 (2,93)	0,053b
<b>Relationship with the ASAN</b> - Yes - No	-	33 (40,7) 48 (59,3)	18 (40,9) 26 (59,1)	0,849a

PNA – pyriform notch angle, NLD – nasolacrimal duct, ASAN – anterior superior alveolar nerve, PLR – prelacrimal recess, MS – maxillary sinus, SD – standard deviation. Significance level: p = 0.05. a – Chi-square test; b – T-test for independent samples.

Table 3   Comparison of results by the PLR type				
Variable	Type I (16 sides)	Type II (94 sides)	Type III (15 sides)	p-value
PLR location - Previous - Sideview	4 (25,0) 12 (75,0)	80 (85,1) 14 (14,9)	15 (100.0) 0 (0,0)	<b>&lt;0,001</b> a
PLR wall thickness - Average (SD)	5,87 (0,51)	2,83 (1,50)	2,00 (0,70)	<b>&lt;0,001</b> b,c
<b>PNA</b> - Average (SD)	39,0 (15,74)	44,04 (11,12)	42,14 (9,98)	<b>0,046</b> b,c
NLD width - Average (SD)	8,45 (2,35)	9,62 (2,68)	10,04 (3,65)	0,190b
<b>Relationship with the ASAN</b> - Yes - No	5 (31,3) 11 (68,8)	40 (42,6) 54 (57,4)	6 (40,0) 9 (60,0)	0,695a

PNA – pyriform notch angle, NLD – nasolacrimal duct, ASAN – anterior superior alveolar nerve, PLR – prelacrimal recess,

MS – maxillary sinus, SD – standard deviation. Significance level: p = 0.05. a – Chi-square test; b – T-test for independent samples.

to classic endoscopic medial maxillectomy of any type, if necessary. The PLR is a space situated in the anteromedial region of the MS, bounded anteriorly by the anterior MS wall, posteriorly by the NLD, laterally by the infraorbital nerve, and medially by the medial

MS wall<sup>6</sup>. Access to this recess requires an initial incision in the mucosa and periosteum of the lateral wall of the nasal fossa. This vertical C-shaped incision should begin at the level of middle turbinate axilla and continue toward a point between the inferior turbinate head and pyriform opening, progressing to open along the floor of the nasal fossa. Subsequently, a mucoperiosteal flap is dissected and medially reflected to the NLD level. Next, an osteotomy is made on the lateral wall of the nasal fossa between the inferior turbinate axilla and the pyriform opening, which can be enlarged, if required. Furthermore, if needed, the bony lacrimal duct lining can be detached and the lacrimal duct can be medially transposed. At the end of the procedure, the mucoperiosteal flap with the inferior turbinate-lacrimal duct complex is repositioned over the lateral wall of the nasal fossa<sup>11</sup>. This method simultaneously spares the inferior turbinate and lacrimal duct, and avoids any injuries.

Some studies have demonstrated that the EPLA is safe and effective for the treatment of benign MS tumors, showing a significantly decreased risk of inverted papilloma recurrence compared to the Caldwell procedure<sup>12, 16</sup>. An additional advantage of using the EPLA instead of the Caldwell approach to treat an inverted papilloma implanted in the anterior MS wall is the preservation of a part of the canine fossa bone and periosteum, which act as a barrier in case of squamous cell carcinoma, preventing its progression to the facial soft tissues<sup>1</sup>.

However, the feasibility of the EPLA depends on a favorable anatomy. The PLR is not always present, such as in cases where the NLD is immediately adjacent to the anterior MS wall. Some studies have shown a great variation in PLR presence, with prevalence rates ranging between 30.9<sup>17</sup>–85.6%<sup>18</sup>. In our sample, PLR was present in 125 of the 150 sides analyzed (83.3%). The variability in the literature may be due to differences between the populations analyzed and lack of assessment of the degree of MS pneumatization in most published studies. According to our results, MS pneumatization appears to be related to the presence of PLR, and PLR is more frequently present in cases where the MS is more pneumatized. Soyal et al.<sup>6</sup> reported a significant difference in PLR occurrence between hypoplastic and normal or hyperplastic sinuses (69% vs. 99%). Thus, different degrees of MS pneumatization may have led to differences in PLR occurrence rates in the literature.

Even if the PLR is present, EPLA may not be possible without some degree of lacrimal duct transposition. PLR<sub>width</sub> is one of the other anatomical factors that may interfere with EPLA. Considering this morphometric PLR parameter, Simmen et al.<sup>14</sup> classified PLR into type I (PLR<sub>width</sub> < 3 mm), type II (3 mm ≤  $PLR_{width} \leq 7$  mm), and type III ( $PLR_{width} > 7$ mm). According to these authors, in addition to providing limited access to the MS in type I PLR, the EPLA also results in greater bone removal and NLD manipulation, making the technique more difficult and increasing the risk of complications. In our sample, most PLR analyzed were type 2 (75.2%) and had an average PLR<sub>width</sub> of 4.90 (± 1.69) mm, indicating that the EPLA was feasible in most cases. According to previous studies, the PLR<sub>width</sub> ranges between 3.7-8.4 mm<sup>6, 14, 18-22</sup>, and some studies have revealed that the Asian population has a greater  $\mathsf{PLR}_{_{width}}$  than the Western population<sup>6, 22</sup>. In this study, no hypoplastic MS had a PLR; thus, we only compared PLR, width between normal and hyperplastic sinuses, and found no significant differences. However, Soyal et al.6 found an association between the MS pneumatization degree and PLR<sub>width</sub>, with less pneumatized MS associated with a significantly lower PLR<sub>width</sub>, more frequently of type I. These findings show that patients with a hypoplastic MS may not be eligible for EPLA. PLR<sub>thick</sub> is an imperative morphometric parameter when considering the EPLA as it represents the level of difficulty in reaching the PLR and guides the choice of instruments to open the bony prelacrimal window<sup>6</sup>. In our sample, PLR<sub>thick</sub> was 3.14 (± 1.86) mm, and the greater the degree of MS pneumatization, the greater the PLR<sub>width</sub> and lower the PLR<sub>thick</sub>. These results are consistent with those of other studies that also reported an association between these variables<sup>6, 7, 20</sup>. Thus, a PLR in hyperplastic MS or a wider PLR will require less effort to penetrate the narrower medial wall of the MS.

In this study, the PLR was anterior to the NLD in 79.2% of the cases, being situated completely lateral to the NLD in only 20.8% of the sides analyzed. This pattern is similar to that reported in the literature<sup>3, 6, 23</sup>. The present study describes a relationship between PLR location and width for the first time, with a wider PLR being more frequently anterior.

The EPLA has a lower complication rate than the Caldwell approach or more extensive endoscopic maxillectomy. Nevertheless, between 15.7-52.4% of patients undergoing this procedure report persistent paresthesia in the ASAN innervation territory<sup>13, 24-26</sup>. The ASAN originates from the anterior two-third of the infraorbital nerve, travels in the sinuous canal along the anterior surface of the maxilla toward its frontal apophysis and pyriform notch, where it branches off and forms the superior dental plexus<sup>9</sup>. The ASAN can be injured during osteotomy of the medial pyriform recess wall, particularly when it is enlarged toward the pyriform notch, which typically happens with a smaller PLR<sub>width</sub>. However, Arosio et al.<sup>13</sup> found no association between PLR<sub>width</sub> and prevalence of postoperative maxillary paresthesia, indicating that this variable is not a good predictor of ASAN injury when analyzed alone. Arosio et al. reported that a PNA with smaller amplitude was associated with a higher incidence of persistent paresthesia in the ASAN territory<sup>13</sup>, defining a cutoff point of 45° for a significantly greater risk of nerve injury. According to them, a smaller amplitude limits MS visualization and access, and requires greater bone removal near the pyriform notch. In our sample, the average PNA amplitude was 43.94° (± 12.14), consistent with the findings of Soyal et al.<sup>6</sup> (42.42° ± 17.32°), but lower than the amplitude reported by Arosio et al<sup>13</sup>. The average PNA amplitude with type I PLR was significantly smaller than that with type II PLR. Soyal et al. reported that the amplitude of type III PLR was significantly greater than that of other types of PLR<sup>6</sup>. These results indicate that the greater the  $PLR_{width}$ , the greater the PNA, reinforcing that PLR<sub>width</sub> is an easyto-measure indicator to select patients for EPLA and predict surgery-related morbidity. Although the study by Arosio et al. recorded no association between PLR<sub>width</sub> and maxillary paresthesia, this result could be due to the underrepresentation of patients with type I PLR<sup>13</sup>, who are considered poor candidates for EPLA, and were thus excluded from the study. Our study proposes a new method to predict ASAN injury based on its position in the frontal process of the maxilla. The ASAN has a relationship with the line parallel to the posterior surface of the anterior MS wall (line A) and the line parallel to the frontal process of the maxilla (line B), two of the key references used to anteriorly enlarge the osteotomy. This nerve is more likely be included in the osteotomy when located posterior to line A or medial to line B, thus being at a greater risk of injury (Figure 6A). Based on these criteria, the ASAN was considered to be in a vulnerable position in 40.8% of the patients in this study, validating the rate of ASAN-related complications reported in the literature. This is the first study to propose ASAN vulnerability criteria, which need to be validated in future studies.

The limitations of this study include a singlecenter design, relatively small sample size, and exclusion of patients with sinonasal disease. Since these are the patients who can benefit the most from the EPLA, future studies should evaluate PLR morphology in patients with sinonasal disease.

# Conclusion

The PLR exhibits a variable anatomy that can influenced by factors such as the degree of MS pneumatization. Nonetheless, this study demonstrates that the PLR is present in most patients and has a sufficient width for enabling an EPLA approach to the MS.

Morphometric parameters, such as the PLR<sub>width</sub>, PNA, and ASAN location, are crucial for

predicting and preventing nerve injury during EPLA. This study proposes an innovative approach to assess the ASAN position and vulnerability. Therefore, preoperative CT assessment is a mandatory patient selection criterion for EPLA.

## **Conflicts of Interest**

The authors declare that there is no conflict of interests regarding the publication of this paper.

### Data Confidentiality

The authors declare having followed the protocols in use at their working center regarding patients' data publication.

#### Protection of humans and animals

The authors declare that the procedures were followed according to the regulations established by the Clinical Research and Ethics Committee and to the 2013 Helsinki Declaration of the World Medical Association.

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# Availability of scientific data

There are no datasets available, publicly related to this work.

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