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Case Report

LIMA PROTOCOL FOR CLEFT PALATE REPAIR IN CLEFT AND CRANIOFACIAL CENTRE CIPTO MANGUNKUSUMO HOSPITAL INDONESIA: A PRELIMINARY STUDY

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ABSTRACT

Background : The techniques of cleft palate repair has faced significant evolutions. More importantly, no surgical protocol has been significantly associated with lower incidence of post-operative complications such as fistula formation, velopharyngeal insufficiency, or speech hypernasality. As cleft width is a strong predictor of outcomes, The Lima Protocol was introduced to select suitable surgical technique based on the degree of severity measured by palatal index. This article aimed to evaluate the efficacy of the newly established Lima Protocol in lowering post-operative complications in primary cleft palate repair surgery in Cleft and Craniofacial Center, Cipto Mangunkusumo Hospital, Jakarta, Indonesia.
Case Presentation : This study is a case series featuring 6 patients with cleft palate treated with primary palatoplasty. Surgical techniques were selected based on the degree of severity measured by Palatal Index. The average age of performing primary palatoplasty was 14 months. 50% of the cases was classified as Veau 2 and the rest was Veau 3. Half of the patients fell into severe category based on Palatal Index and the other half was in moderate group. None of the patients developed fistula formation 3 months post-palatoplasty.
Discussion & Conclusion: We confirmed that the 1-flap technique provided adequate closure comparable with the 2-flap technique without risking mucoperiosteal flap necrosis and fistula formation. Using the strengths of different surgical techniques individualized for each case based on the palatal index and grade of severity is indisputably a practical strategy. Trials with longer follow-ups are required to widely implement The Lima Protocol.
***Keywords**: LIMA Protocol; Palatoplasty; Cleft Palate; Palatal Index*

Latar Belakang: Teknik operasi sumbing lelangit telah mengalami evolusi yang signifikan. Sampai saat ini, belum ada protokol operasi sumbing lelangit yang dapat mengurangi insidensi komplikasi pasca operasi seperti pembentukan fistula, insufisiensi velofaringeal, atau hipernasalitas fungsi bicara. Karena lebar celah terbukti merupakan prediktor luaran yang significan, Protokol Lima diperkenalkan sebagai dasar pemilihan teknik operasi berdasarkan tingkat keparahan celah yang diukur dengan indeks palatum. Artikel ini bertujuan untuk mengevaluasi efektifitas Protokol Lima dalam menurunkan insidensi komplikasi pasca operasi sumbing lelangit primer di Cleft and Craniofacial Center, Rumah Sakit Cipto Mangunkusumo, Jakarta, Indonesia.
Presentasi Kasus: Penelitian ini menunjukkan 6 pasien dengan celah lelangit yang menjalankan palatoplasti primer. Teknik operasi dipilih berdasarkan derajat keparahan celah yang diukur dengan Index Palatum. Usia rata-rata pasien melakukan palatoplasti primer adalah 14 bulan. 50% kasus diklasifikasikan sebagai Veau 2 dan sisanya adalah Veau 3. Separuh dari pasien termasuk dalam kategori parah berdasarkan Indeks Palatum dan setengah lainnya adalah kategori sedang. Tak satu pun dari pasien menunjukkan terbentuknya fistula palatum 3 bulan pasca-palatoplasti.
Diskusi & Kesimpulan: Kami mengkonfirmasi bahwa teknik 1-flap dapat menutup celah dengan baik sebanding dengan teknik 2-flap tanpa peningkatan risiko nekrosis flap mukoperiosteal dan pembentukan fistula palatum. Mengaplikasikan teknik operasi yang disesuaikan dengan kebutuhan masing-masing pasien untuk kasus berbeda berdasarkan indeks palatum dan tingkat keparahan celah merupakan strategi praktis dengan luaran yang baik Penelitian lanjutan dengan masa observasi yang lebih lama diperlukan untuk mengimplementasikan Protokol Lima secara luas untuk strategi perbaikan celah lelangit.
***Kata Kunci:** Protokol LIMA; Palatoplasti; Celah Lelangit; Indeks Palatum*

Conflicts of Interest Statement:
The author(s) listed in this manuscript declare the absence of any conflict of interest on the subject matter or materials discussed.

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INTRODUCTION

Palate repair has faced considerable modifications globally and a lot of techniques are currently used depending on the indications and operator's expertise.[1] One-stage repair is performed in more than 90% of cleft palate surgeries than the two-stage repair, although both still have their own standing and followers worldwide.[2] Early and delayed timing for palate repair was also highly debatable, in relation to maxillary hypoplasia, speech outcome, and post-operative complications such as fistula formation and velopharyngeal insufficiency (VPI).[3] The best technique remains controversial and their efficacy is always under a strict argument.

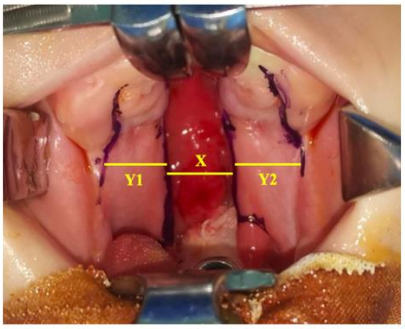
The longstanding Veau classification, the most commonly used for cleft lip and palate evaluation, was believed to be impractical to guide surgeons in selecting appropriate surgical techniques. Moreover, cleft lip and palates appear to be phenotypically diverse and complicated, making classifications challenging and difficult.[4] Most surgeons also comfortably stick to one technique for all without putting the cleft width and cleft type into consideration when choosing the surgical approach.

Rossell-Perry first popularized the new paradigm of cleft palate repair principle. Instead of classifying the palate anomaly based on the affected anatomical segment (Veau), he proposed the ideas of choosing the surgical procedures based on the severity of the cleft gap and distortion.[5] The Lima Protocol was introduced to evaluate the severity of cleft palate based on the degree of hypoplasia, which was then used to select which surgical techniques suit best for the proposed classification, combining the strengths of both 1-and 2-stage palatoplasty.

The cleft palate index is the key tool to calculate the severity of the cleft in The Lima Protocol. The index is obtained by comparing the cleft's width (X) with the total width of right and left palatal segment diameters (Y1+Y2) as displayed in Figure 1. Selection of the surgical techniques was individualized based on the cleft type and palatal index, which is classified into three categories: mild (index 0-0.2), moderate (0.2-0.4), and severe (>0.4). This study aims to evaluate the efficacy of Lima Protocol in lowering post-operative complication in primary cleft palate repair surgery in Cleft and Craniofacial Center, Cipto Mangunkusumo Hospital, Jakarta.

Table 1. Surgical techniques selection based on Veau cleft palate classification as proposed in the Lima Protocol by Rossell-Perry

Cleft Palate Type	Surgical Technique
Veau I and II (mild)	Furlow Technique
Veau II (moderate)	Hybrid Palatoplasty
Veau II (severe)	Von Langenbeck Technique
Veau III (mild)	Hybrid Palatoplasty
Veau III (moderate)	One-flap Palatoplasty
Veau III (severe)	One-flap + Hybrid Palatoplasty
Veau IV (mild)	Hybrid Palatoplasty
Veau IV (moderate)	Von Langenbeck Technique
Veau IV (severe)	2 stage Palatoplasty (Malek) + Von Langenbeck



$$Palatal\ Index = \frac{X}{Y1 + Y2}$$

X = cleft's width
Y = palatal segment diameter (right and left; in mm)

Figure 1. The schematic formula of Palatal Index introduced in the Lima Protocol.Note that Palatal index is the ratio of the cleft gap and the addition of both right and left palatal flap segment diameter, which then is classified into three categories: mild (index 0-0.2), moderate (0.2-0.4), and severe (>0.4).

METHOD

This is a case series featuring the implementation of Lima Protocol to select suitable surgical techniques for cleft palate repair in patients with non-syndromic cleft palate. 6 Patients with cleft palate from our institution were enrolled in the study by receiving the first

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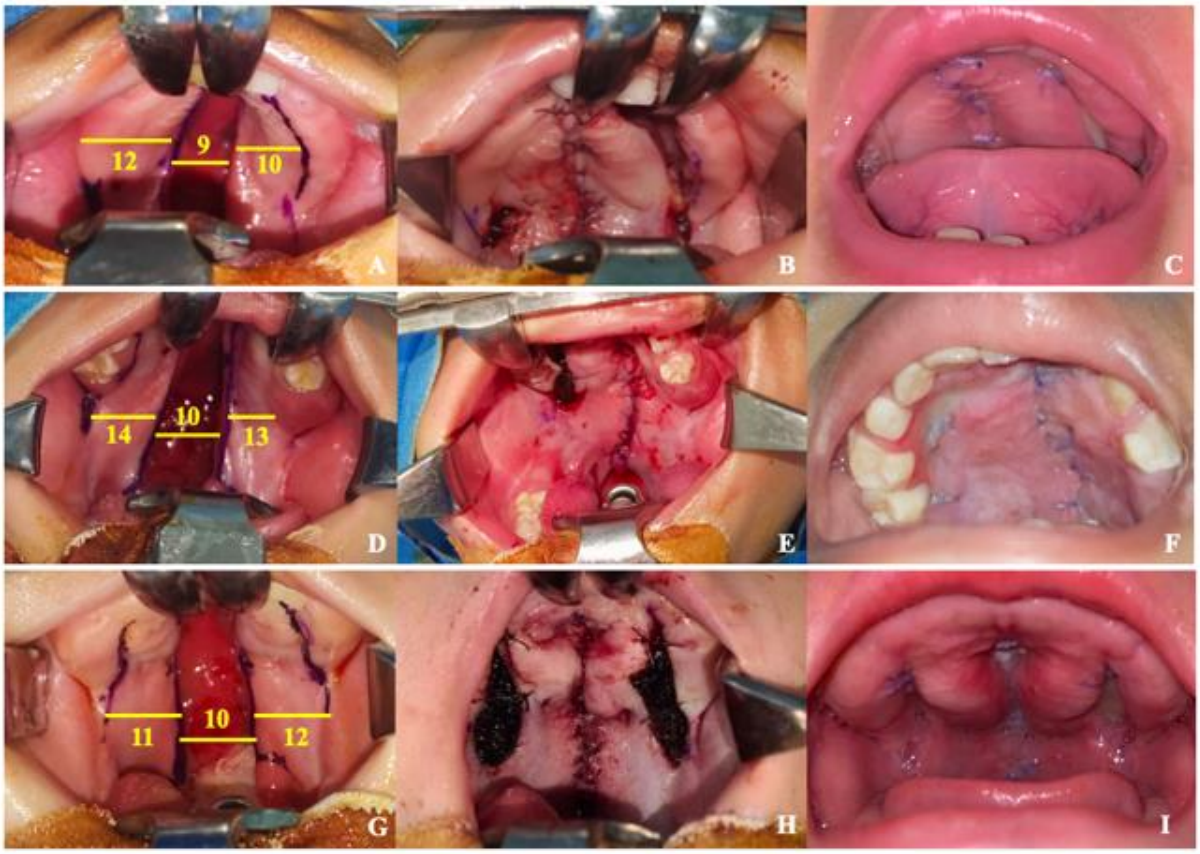

Figure 2. Representative of the cleft palate cases treated according to the Lima Protocol.
A). A 13-month-old patient had Veau 3 cleft palate and 0.41 Palatal Index classified as severe unilateral cleft palate (Lima classification) with details of cleft width and flap width displayed above in millimetres;
B). Post-operative view after hybrid palatoplasty was performed incorporating the one flap technique and lateral relaxing incision;
C). 3 weeks post-operative view of the hard palate showed no fistula formation;
D) A 24-month-old patient had Veau 3 cleft palate and 0.37 Palatal Index classified as moderate unilateral cleft palate (Lima classification) with details of cleft width and flap width displayed above in millimetres; E). Post-operative view after one flap palatoplasty was performed showing adequate closure of the hard palate;
F). 3 weeks post-operative view of the hard palate showed no fistula formation and aesthetically pleasing result.
G) A 9-month-old patient had Veau 2 cleft palate and 0.43 Palatal Index classified as severe incomplete cleft palate (Lima classification) with details of cleft width and flap width displayed above in millimetres; H). Post-operative view after Von Langenbeck palatoplasty was performed showing lateral relaxing incision on both sides; I). 2 weeks post-operative view of the hard palate showed no fistula formation.

ever surgery performed based on the Palatal Index calculation. Inclusion criteria includes all non-syndromic cleft patients with varying cleft types and cleft gap width. The outcome of the evaluation feature post-operative fistula formation.

The patient characteristics of this study are presented in Table 2. 6 patients with average age of 14 months old, ranging from 9 to 24 months, participated in this preliminary study. 3 of them had Veau 3 cleft palate and the rest was categorized as Veau 2. Palatal Index was calculated for each patient, 50% was classified as severe based on the Palatal Index and the rest was in the moderate severity group. We performed one-flap technique, von Langenback, and hybrid palatoplasty. The hybrid technique incorporated either one-flap or Furlow technique combined with one lateral relaxing incision on the cleft side, preserving the non-cleft-side flap. No fistula formation was observed 3 weeks following the primary palatoplasty (see Figure 2).

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Table 2. Characteristics of patients with cleft palate operated using the Lima Protocol

Patient	Age (mo)	Veau Classification	Cleft width (mm)	Right flap (mm)	Left Flap (mm)	Palatal Index	Lima Classification	Surgical Technique	Fistula*
1	13	Veau 3	9,0	12,0	10,0	0,41	Severe unilateral CP	Hybrid Palatoplasty**	(-)
2	16	Veau 2	10,0	12,0	12,5	0,41	Severe incomplete CP	Von Langenbeck Palatoplasty	(-)
3	24	Veau 3	10,0	14,0	13,0	0,37	Moderate unilateral CP	One Flap Palatoplasty	(-)
4	9	Veau 2	10,0	11,0	12,0	0,43	Severe incomplete CP	Von Langenbeck Palatoplasty	(-)
5	10	Veau 2	5,0	12,0	10,0	0,23	Moderate incomplete CP	Hybrid Palatoplasty***	(-)
6	12	Veau 3	8,0	13,0	11,0	0,33	Moderate unilateral CP	Hybrid Palatoplasty**	(-)

Legend: CP=Cleft Palate; mo= month;
*= Fistula evaluated 3 weeks post-operation;
**= 1-flap palatoplasty + lateral relaxing incision;
***= Furlow technique + lateral relaxing incision

DISCUSSION

The Lima Protocol is a practical strategy to select suitable surgical techniques based on the degree of severity determined by the Palatal Index that measures the ratio of available mucoperiosteal flap and cleft width, which is the vital predictor of palatoplasty outcomes. Through this study, we proposed that 1-stage repair appears to be the safest, most time-and cost-efficient technique for cleft palate repair, although 2-stage repair is sometimes reserved for cases with massive cleft width. Increased rate of fistula formation following palatoplasty was observed in 2-stage technique, which necessitates additional fistula surgical repair.[6, 7]

We also demonstrated the superiority of one-flap technique for closure of cleft palate in terms of clinical appearance. In fact, 2-flap palatoplasty is the most often used one-time surgical technique for cleft palate repair because it allows closure und under minimal tension and lowers the rate of subsequent fistula formation.[8] However, the extent of dissection on both sides leaving raw lateral surfaces poses detrimental risk to maxillary growth. One study showed that the use of 1-flap technique minimized this risk and provided comparable outcome to those of a 2-flap technique in terms of hypernasal speech and postoperative fistula occurrence.[9]

Rossell-Perry and colleague in their study compared the conventional two-flap Bardach technique with the Lima Protocol approach that favors 1-flap palatoplasty. Results showed no significant difference between both groups in terms of formation of fistula and VPI post-operatively. The same study showed that the Lima Protocol significantly reduced the incidence of flap necrosis rate following primary palatoplasty.[5]

Combining lateral relaxing incisions ensures the non-tension closure of the cleft palate, reducing the risk of mucoperiosteal flap necrosis. Previously, allowing lateral relaxing incision was thought to promote maxillary hypoplasia as extensive dissection of hard palate disrupts maxillary growth.[10] Rossel-Perry and colleagues in their study statistically confirmed that development of maxillary growth is multifactorial and is not solely associated with any protocol or the use of lateral relaxing

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incisions.[11] A systematic review showed that the 2-stage protocols do not prevent the occurrence of maxillary hypoplasia.[12] In contrast, incorporating relaxing incision in the 1-stage protocol are correlated with lower fistula rate and better speech.

Several studies confirmed that an association between the extent of clefting (cleft width) and post-operative complications existed.[13] Insufficient mucoperiosteal tissue to close the defect due to the wide cleft gap is the potential contributor. In the present study, we found no fistula formation 3 weeks post-operatively, suggesting that palatal index is a good indicator of surgical techniques selections and surgical outcomes. We demonstrated the efficacy of 1-flap technique in closing the cleft gap with good anatomic and functional palatal closure albeit the less surgical dissection. Furthermore, the bleeding episodes were also minimized due to the less extensive dissection compared to the 2-flap technique.

Our preliminary study, although analyzed not long after the surgeries were performed, showed highly promising results. Longer follow up time would be beneficial in further studies to reveal the efficacy of Lima Protocol in minimizing the incidence of velopharyngeal insufficiency and mucoperiosteal flap necrosis, as well as favoring aesthetic outcome. A controlled trial is also encouraged to provide further comparison between the Lima Protocol and other long-established surgical strategy.

CONCLUSION

The Lima Protocol for cleft palate repair serves as a valuable operative strategy by incorporating individualized surgical techniques based on the severity of the cleft measured by The Palatal Index. We observed promising results in this preliminary study with regards to fistula formation in patients with non-syndromic cleft palate. Further trials are required to widely implement The Lima Protocol in our institution, one of the established cleft and craniofacial center in one of developing countries.

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SUBMISSION VERIFICATION

All authors confirmed that all content of this manuscript has not been published nor under consideration for published work elsewhere. The work was presented in 24th Annual Scientific Meeting of Indonesian Association of Plastic Reconstructive and Aesthetic Surgery (InaPras) as oral presentation (Indonesia, June 2nd 2021). The authors contributed equal amount of work from the idea concepting, actuating, analysing, writing, until process of editing. This paper was approved by all authors and we fully guarantee its novelty.

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