SPECIAL TOPIC

Is The 'Rule of Tens' a Necessary Screening Criteria in Cleft Lip Surgeries

Ibadurahman*, Gentur Sudjatmiko**
Jakarta, Indonesia.

Background: The "rule of tens" (ROT) is still widely applied nowadays in many cleft centers worldwide for cleft lip surgery, although many surgeons do not implement it as a standard ru Recent advances in the field of anesthesiology have enhanced the safety of surgery for neonates. In Indonesia, ROT is still applied but is still flexible, due to some pertaining social conflicts. The relevance of ROT to the rate of mortality and morbidity is still unknown. This study aims to assess the need of using ROT in cleft lip surgeries.
Methods: A retrospective study was conducted. Data was obtained from the medical records of patients who had undergone cleft lip repair between January 2004 to December 2005 in one day care setting. All data related to ROT parameters was categorized in two groups, either fit or unfit according to ROT criterias. The relationship of ROT to rate of associated morbidity and mortality was evaluated.
Results: There were 204 cases of cleft lip repair with age range of 6-week to 12-year old. More than half (52.9%) was unfit for ROT. There were twelve cases of wound dehiscence and one total breakdown of the sutures, and no mortality. There were no statistically significant correlation ce between ROT and the rate of dehiscence.
Conclusion: ROT is not a definitive criterion that could predict the success of cleft lip repair surgery.
Key words: *Rule of ten, cleft lip surgery*

Latar Belakang: Hingga saat ini "*rule of tens*" (ROT) masih diterapkan di berbagai pusat bedah bibir sumbing di dunia, meski banyak ahli bedah yang tidak menggunakannya sebagai acuan. Saat ini kemajuan dalam bidang anestesiologi telah meningkatkan kemungkinan untuk melakukan operasi pada neonatus secara aman. Di Indonesia ROT masih diterapkan meski tidak secara kaku karena berbagai masalah sosial. Hubungan antara implementasi ROT dengan mortalitas dan morbiditas masih belum diketahui. Tujuan penelitian ini adalah untuk menilai perlu tidaknya menggunakan ROT dalam menentukan kapan melakukan bibir sumbing.
Metode: Penelitian ini adalah studi retrospektif berdasarkan data dari rekam medik pasien-pasien yang menjalani operasi bibir sumbing antara Januari 2004 hingga Desember 2005 pada unit rawat sehari. Semua data yang berhubungan dengan ROT dibagi dalam 2 kelompok, sesuai atau tidak sesuai dengan kriteria ROT. Evaluasi terhadap hubungan ROT dengan morbiditas dan mortalitas dianalisa.
Hasil: Terdapat 204 kasus operasi bibir sumbing dengan rentang usia antara 6 minggu hingga 12 tahun. Lebih dari setengah (52.9%) tidak memenuhi kriteria ROT. Terdapat 12 kasus dehisensi, satu kasus dengan jahitan yang terlepas, dan tidak didapati mortalitas. Tidak terdapat hubungan yang bermakna secara statistik antara ROT dan tingkat dehisensi.
Kesimpulan: ROT bukan kriteria yang kaku yang dapat memprediksi kesuksesan pembedahan.
Kata kunci: *Rule of ten, cleft lip surgery*

For many years, surgeons have had different opinions about the best timing for cleft lip repair and the controversies is still ongoing.[1] Most of them use the "rule of tens" (ROT) as a standard criteria to determine when to operate on a cleft lip deformity.[2] But we know of at least 6 centers in the world who routinely perform cleft lip repairs during the first two weeks of infant's life. This is facilitated by the recent advances in the field of pediatric anesthesiolgy which enables the sedation of infants, with only minimal postoperative complications.[3-8]

Some criterions that had been established as a guide to determine the timing of cleft lip surgery are age, weight, hemoglobin

*From Departement of Surgery University of Indonesia Cipto Mangunkusumo Hospital, Jakarta, Indonesia.**
*From Division of Plastic Reconstructive, and Aesthetic Surgery University of Indonesia Cipto Mangunkusumo Hospital, Jakarta, Indonesia.***

Disclosure: *The authors have no financial interest to declare in relation to the content of this article.*

and leukocyte counts. Wilhelmsen and Mushgrave proposed the "rule of 10" in 1966 which include (1) infant's body weight of 10 pound, (2) hemoglobin count of 10 g/dl, and (3) leukocytes less than 10.000/ul.[9] Then in 1967, Millard proposed a similar criteria which was named the "rule of over ten" with stated that infants subjected to cleft lip surgery must at least weigh 10 pound, hemoglobin level over 10 g/dl, and aged older than 10 weeks. [1]

In The School of Medicine University of Indonesia, Cipto Mangunkusumo General Hospital Jakarta, Rules of Ten and Rules of Over Ten had been applied in cleft lip patient selections, although still flexibly adjusted. Most of the patients came from rural area with low social economic level, and the fund provider was not prepared to provide for their stay in the city, or transport back and forth from their homes if the patient's surgery had to be cancelled on that trip. Hence surgeons were reluctant to cancel the surgery since that first meeting may be the patient's only chance for surgery. However, no study to date have assessed or evaluated the advantages of adhering to the parameters used in the ROT in daily practice. A study in 2004 by a colleague in the Pediatric Surgery Division revealed that more than 50% of patients with cleft lip had anemia.[10] Hence indicating that without specific perioperative preparation at least 50% of these children failed to fulfill ROT criteria in a random screening. A question arose, and this study aim to assess the significance of abiding to ROT criteria in cleft lip repairs, and how failing to follow such rules affect the results of cleft surgeries.

This study retrospectively analyze all cases of cleft lip repair in our hospital during a two year period, taking into account the variables related to the ROT criteria, and evaluate whether the incidence of postoperative morbidity and mortality is associated to adhering to such rule.

METHODS

All patients who underwent cleft lip (CL) repair for the first time in our One Day Care Unit at Division of Plastic Surgery Department of Surgery Cipto Mangunkusumo Hospital from January 2004 until December 2005 were reviewed. Registration charts and medical records were evaluated until a follow up period of 3 months. Variables noted included identity, gender, age, diagnosis, body weight, hemoglobin and leukocyte count, date of procedure, co-morbidity, rate of wound dehiscence, other complication and mortality rate. Repair technique was either by the Millard technique or its modifications.[11] Major dehiscence was defined as a complete breakdown of the suture which requires reoperation for correction. Minor dehiscence was defined as less than major suture breakdown with no need for reoperation specifically for this problem.

ROT was defined as age ≥ 10 weeks (2.5 month), weight ≥ 10 pound (4.5 kg), hemoglobin ≥ 10g/dl and leukocytes ≤ 10.000/uL. Accordingly, the patients were divided into two groups, either fit or unfit according to the ROT criterions. Statistical analysis (chi square test is for nonparametric and student t test for parametric data) was performed to assess the differences in complication rates, other morbidity and mortality between the two groups. Significance is set at p value < 0.05.

RESULT

There were a total 204 patients, 112 boys and 92 girls, aged 6-weeks to 12-year old. Almost 56% of the patients (114 infants) had surgery at age 2.5 months to 6 months (Figure 1). Sixty nine patients (33.8%) were diagnosed with cleft lip (CL) and 135 patients (66.2 %) with cleft lip and palate (CLP). All patients weighed above 10 pound (4.5 kg). The lowest hemoglobin count was 7.4 g/dL, and 16.2% of all patients had a hemoglobin count lower than 10.0 g/dL. The range of hemoglobin level is presented in Figure 2. The highest leucocyte count in the series was 24,800/uL, with 33.30% of patients displaying leucocytes count above 10,000/uL (27.90% between 10,000-14,999/uL, 4.90% between 15,000-19,999, and 0.50% above 20,000/uL).

We found that 108 patients (52.9%) were unfit for the ROT criteria. Among patients who did not fulfill ROT criteria,

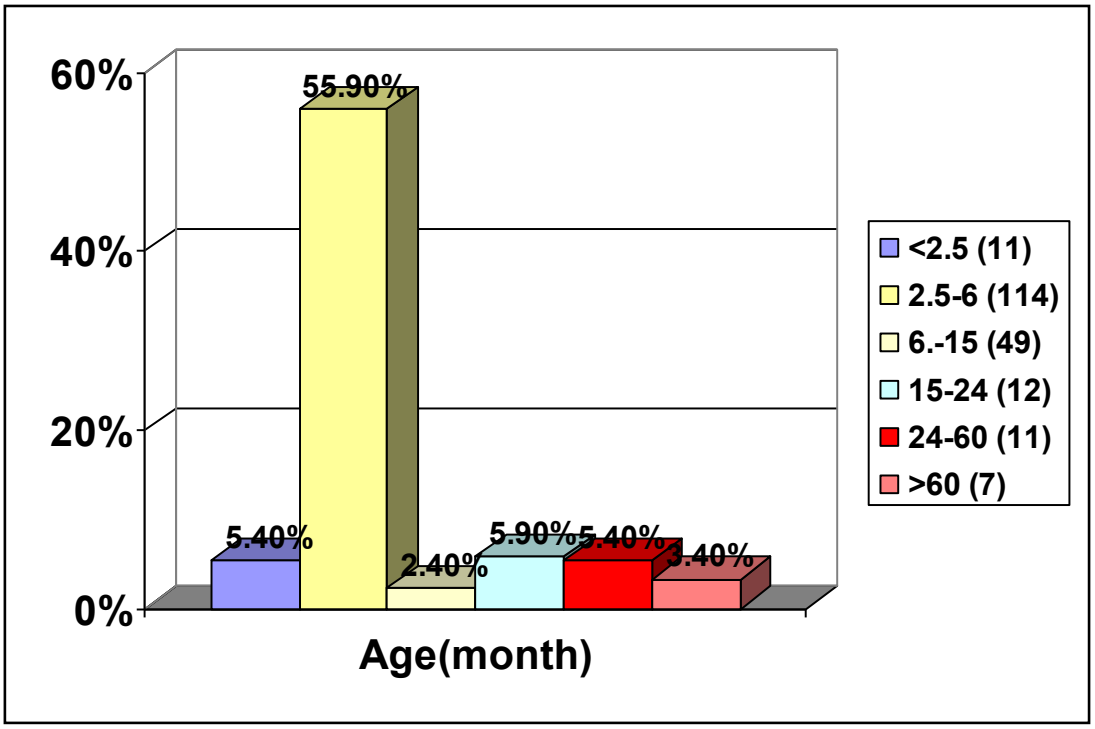

Figure 1. Distribution in timing of surgery. Most patients (55.9%) were operated between the age of 10 weeks to 6 months.

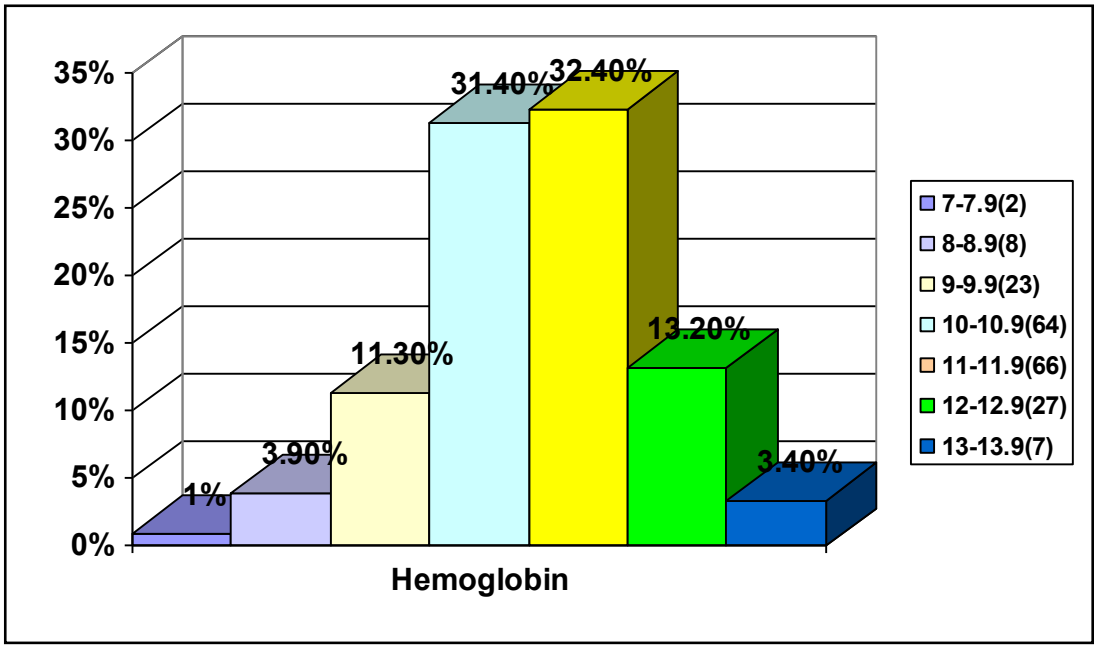

Figure 2. Distribution of hemoglobin level. Hemoglobin count was between 10-12 g/dl in 63.8% of patients.

10.2% were aged below 10-week, 37% had hemoglobin level below 10 g/dl, and 77.8% had leucocytes count above 10.000/ul. About 14 patients (6.9%) still proceeded to surgery although they were suffering from mild respiratory tract infection with American Society of Anesthesiologists (ASA) score of 1 to 2, ten of them with CLP and 4 with CL.

No mortality was found in this series. There were 12 cases (5.9%) of wound dehiscence with one case (0.49%) of major dehiscence with total breakdown of sutures. The 12 cases with complications are enlisted in Table 1. From this dehiscence group, 75% were with CLP and 25% were CL cases. 58.3% patients were unfit according to the ROT, 41.7% had leukocytosis and 25% had hemoglobin count below 10 g/dl. The youngest patient in this group was 10-week old weighing more than 10 pounds, with a hemoglobin level of 8.7 g/dl. Effect of surgical technique, gap of cleft, and skill of surgeon could not be evaluated due to incomplete data.

Further analysis seem to display that patients with CLP were more susceptible to local complication, but the difference was statistically not significant. CLP patients were aslo operated earlier than CL patients (10 vs. 13 months). Patients who were unfit according to ROT displayed a trend of being more susceptible to dehiscence but this was statistically insignificant. No difference was found between patients who underwent surgery below 10-week old and patients older than 10 weeks in relation to complication. Patients with hemoglobin and leucocyte level unfit to ROT was more susceptible to wound dehiscence but were statistically not significant. Weight was the only parameter in the patient series which abide 100% to the ROT, because all patients weighed more than 10 lbs.

Further statistical analysis showed that none of the parametric variable of ROT has impact to complication rate. Some other laboratory parameters were almost routinely performed such as platelet count, bleeding/ clotting time (in 83.2% and 64.8% of patients respectively), but were not analyzed as deemed irrelevant to the ROT criteria. Blood glucose, albumin and hemostasis were tested only with indication in one patient.

Table 1. Profile of patients with postoperative complication

No	Diagnosis	Age (month)	Weight (kg)	Hemoglobin (g/dl)	Leucocyte (/ul)	Complication
1	CLP	2.5	5.5	8.7	3.700	Minor dehiscence
2	CLP	2.5	7.5	10.2	7.900	Minor dehiscence
3	CLP	3	5.5	9.2	4.900	Minor dehiscence
4	CLP	3	5.5	12.1	8.800	Minor dehiscence
5	CLP	3	5.1	10.2	11.000	Major dehiscence
6	CL	3	6	11.9	10.200	Minor dehiscence
7	CLP	3.5	6	10.1	5.800	Minor dehiscence
8	CLP	4	9.7	11.3	6.500	Minor dehiscence
9	CLP	5	6	11.8	10.600	Minor dehiscence
10	CLP	13	5.2	9.9	11.700	Minor dehiscence
11	CL	60	14	11.4	8.800	Minor dehiscence
12	CL	60	13	10.7	11.700	Minor dehiscence

DISCUSSION

ROT as a guide in cleft lip repair had been applied worldwide since introduced by Mushgrave and Millard. But now at least 6 internationally-known cleft centers operates routinely on this deformity within the first 2 weeks of life.[3-8] Few studies have directly evaluated the implication of implementing this rule, in relationship with the rate of postoperative complications. We review a total of 204 cases of cleft lip surgery performed in our center during a one-year period, their adherence to the ROT and how it affect the rate of complications following surgery.

Demographically found in this study, boys are more susceptible to CL and CLP than girls, in line with a study done in Britain in 1960 and in Korea in 1980. However this factor is demographic factor dependent. For instance, in Iran there was a different pattern with boys were more susceptible to CLP only.[12-13]This study is also demographically in line with other studies in the incidence of cleft lip alone or those with cleft palate. Almost 67% (66.7%) of the cases were CLP and the rest were CL. In many studies, the proportion of CLP were between 57.4%-68.2% and the rest were CL.[13-17]

In this study children with CLP are prone to be lighter in weight than CL (7.2 vs. 7.4 kg). This may be the consequence of feeding difficulties and susceptibility to infection due to a more severe defect.[18] On the other side, CLP was repaired earlier than CL (10 month vs. 14 month). This would be the result of more parental concern to a more severe defect and difficulties, although the operative timing is still later than ideal. A retrospective study in Southeast Africa with 640 cases of cleft for 20 years concluded that operative timing in CLP influence weight. If repair was performed after one year the child would be more susceptible to underweight.

Like our recent study, this study also confirmed that the type of cleft would influence weight on operative timing.[19] It's very recommended to repair cleft before one-year of age to achieve better nutritional status, better speech ability, and reduce the incidence of middle ear infection.[20-21]

In this study we found that for cleft lip repair most of the infants (55.4%) were operated between 3-6 months, only 5.4% were operated before 3 months and the rest (39.2%) after 6 months. This result is different to the Korean study in which 54.1 % cleft lips were already operated in the first 3 months of life.[13] A survey of unilateral cleft lip timing and technique had been performed in US involving 224 cleft centers in the US and 34 international cleft centers. The result was that 33.3% were operated before 3 months, 65.9% between 3-6 months and the rest (0.7%) after 6 month. The technique that was mostly used was Millard's in 84.2% of cases.[22] Neonatal cleft lip repair is safer now due to advances in anesthesiology with low complication post anesthesia. Some benefits of earlier repair are reduced parent's anxiety, accelerated achievement of normal feeding process, and offer distinct advantages to the parents and child.[9]

Recommendations for safe practice include the selection of gestationally mature infants with no intercurrents illness, avoidance of opioid analgesia, adequate staffing ratios of experienced postoperative nursing care and appropriate monitoring including oximetry and apnea detectors.[23]

In the present study, there were no neonates at all, but there were no local morbidity and mortality in 11 babies below 10 weeks. It seems that no matter whether ROT fit or unfit for age, the repair can be performed as long as safety is guaranteed.

In this study 52.9% of the patients were unfit according to the ROT criteria, but the local complication rate (dehiscence) was low (5.8%) and total suture breakdown was 0.49%, with zero mortality rate. The incidence of local infection and dehiscence of lip closure varies in the literature from 1 to 7.4%.[24] An older study by Mushgrave and Wilhelmsen in 1966 evaluating 585 cases of cleft lip repair over 15 years revealed 22 cases of minor dehiscence (3.8%) , 5 cases of major dehiscence (0.85%), and 2 cases of mortality (0.34%). In their study, 18.6% patients were unfit to the ROT, and the total complication rate was 5-fold compared to the other group following the ROT.[9]

Fever and leucocytoses are signs of infection. Surgeon and anesthesiologists would consider postponing the operation because no one favors operating on sick children in an elective setting. Takemura et al recommended postponing the CLP repair if there were signs and symptoms of common cold. This concerns the susceptibility to perioperative respiratory complications such as laryngospasm, hypersecretion, desaturation, and cough. Takemura used a "common cold score" that was introduced by Mizushima and Satoyoshi.[25] The borderline and high risk groups were more prone to respiratory complications than the healthy group. Leucocytoses only was just one of the sign of infection, according to the "common cold score" leucocytoses alone does not disqualify a child as unfit for surgery.

More than 15% patients in this study had hemoglobin count below 10 g/dL and no statistical difference in relation to local complication was found compared to those with hemoglobin level above 10 g/dL. A similar study which looked at the relationship of hemoglobin count to respiratory and cardiovascular complications reviewed 200 cases of children between 3-month and 5-year old was done in Srilanka in 1999. This study found that there were no difference in the perioperative respiratory and cardiovascular complications between children with hemoglobin count 7-10 g/dl and above 10 g/dl.[27] The question whether a perioperative hemoglobin test is necessary prior to surgery in low risk patiens with ASA 1 to 2 was further studied by Olson, Stone and Lubarsky. They retrospectively studied 9584 cases, including infants, and found that it was not necessary to routinely test preoperative hemoglobin count in outpatient surgery candidates with ASA 1-2.

The reason was the low incidence of anemia detected in that group, and if anemia was confirmed there was no change of therapy.[28] Good clinical assessment of the patients is more important than routine preoperative laboratory screening that should be performed only if there is a clear clinical indication.[29] Barcelona, Cote and Thomson recommended postponing preterm infant elective surgery if the hemoglobin count is below 9 g/dl and in term infants if below 7 g/dl.[30] This is related to the low capability of the infant myocardium to respond to reduction in tissue oxygen delivery, making it susceptible to ischemia.[31]

There is no universal agreement in regard to the best timing to operate on CL and CLP. These deformities are not a simple cosmetic deformity, but a complex problem which requires the involvement of a large number of different specialty. It has been known that about 300 syndromes and multiple congenital anomalies are related to CL and CLP. About 20% of cleft coexists with other congenital abnormality. About 70% of patients with CLP are nonsyndromic but majority of CP are syndromic.[32] In preoperative evaluation, the existence of other congenital abnormalities and syndromes and the possibilities to difficult intubation must be taken into consideration.[33]

CONCLUSION

From the 4 parameters of ROT, only weight had been applied to all 204 patients. Age, hemoglobin and leucocyte levels vary in value without any significant difference in complication. Hence the rule of 10 should not be rigidly used as a criteria that could predict the success of the operation. We hope to formulate our own rule specified to our pertaining demographic and social conditions.

We propose 5 important parameters to evaluate in patient selections, which include (1) nutritional status (weight according to age), (2) volume/thickness of the tissue (lip or palate) and distance of the gap, (3) hemoglobin level higher than 9g/dL (in line with Barcelona, Cote and Thomson[30]), (4) body temperature below 37.5^{o}C, (5) and presence or absence of respiratory tract condition.

Gentur Sudjatmiko, MD
Division of Plastic surgery
Cipto Mangunkusumo General Hospital, Jakarta
dr_gentur@yahoo.co.id

REFERENCES

1. Millard DR. Optimum time for cleft lip surgery. In: Cleft craft, the evolution of its surgery: The unilateral deformity. 1st ed. Boston: Little Brown; 1976. p. 69-74.
2. American Cleft Palate Craniofacial Association. Core curriculum for cleft lip/palate and other craniofacial anomalies: a guide for educators. 2004.
3. Bromley GS, Rothaus KO, Goulian D. Cleft lip: Morbidity and mortality in early repair. Ann Plast Surg 1983; 10:214-16.
4. Denk MJ, Sanchez J, Calloway D. Immediate repair of cleft lip and palate in the neonate: A beneficial approach. Presented at Southeastern Society of Plastic and Reconstructive Surgery, Hilton Head, SC, June, 1993
5. Desai SN. Cleft lip repair in newborn babies. Ann R Coll Surg Engl 1990; 72(2):101-103.
6. Freedlandler E, Webster MHC, Lewis RB, Blair M, Knight S, Brown AI. Neonatal cleft lip repair in Ayrshire; a contribution to the debate. Br J Plast Surg 1990; 43(2):197-202.
7. Nakajima T, Yoshimura Y: Early repair of unilateral cleft lip employing a small triangular flap method and primary nasal correction. Br J Plast Surg 1993; 46:616-617.
8. Van Boven MJ, Pendeville PE, Veyckerrans F. Neonatal cleft lip repair: The anesthesiologist's point of view. Cleft Palate Craniofac J 1993; 30:574-76.
9. Wilhelmsen HR, Musgrave R H. Complication of Cleft Lip Surgery.Cleft Palate J 1966; 3(7): 223-31.
10. Irhamni. Status gizi pasien balita sumbing bibir dan palatum di beberapa tempat pilihan di Indonesia, 2004. Unpublished.
11. Hopper RA, Cutting C, Grayson B. Cleft Lip and Palate. Dalam Thorne CH, Beasley RW, Aston SJ, Bartlett SP, Gurtner GC, Spear SL, editors. Grabb and Smith's Plastic Surgery. 6th ed. Lippincott Willias & Wilkins. Philadelphia: 2007. p. 208-13.
12. Shin KS, Lee YH, Lew JD. Cleft lip and cleft palate in Korea, 2422 cases in 20 years. Yonsei Medical Journal 1985; 26(2):184-90.
13. Rajabain MH, Sherkat M. An Epidemiologic Study of Oral Clefts in Iran: Analysis of 1669 Cases. Cleft Palate Craniofac J 2000; 37(2):191-96.
14. DeMey A, Vadoud-Seyed JP, Demol F , Govaerts M. Early postoperative complications in primary cleft lip and palate surgery. Eur J Plast Surg 1997; 20:77-79.
15. Lees VC, Piggot RW. Early postoperative complications in primary cleft lip and palate surgery - how soon may we discharge patients from hospital? Br J Plas Surg 1992; 45:232-34.
16. Harville EW, Wilcox AJ, Terje RL, Vindenes H, Abyholm F. Cleft Lip and Palate versus Cleft Lip Only: Are They Distinct Defects? Am J Epidemiol 2005; 162:448-53.
17. Natsume N, Kawai T, Kohama G, Teshima T, Kochi S, Ohashi Y et al. Incidence of cleft lip or palate in 303738 Japanese babies born between 1994 and 1995. Br J Oral Maxillofac Surg 2000; 38:605–607
18. Gopinath VK, Wan Muda AM. Assesment of growth and feeding practices in children with cleft lip and palate. Southeast Asian J Trop Med public Health 2005; 36:254-8.
19. Lazarus DD, Hudson A, Fleming A, Goddard E, Fernandez A. Are children with clefts underweight for age at the time of primary Surgery? Plast Reconstr Surg 1999; 103(6):1624-1629.
20. Grobbelaar AO, Hudson DA, Fernandes DB, Lentin R. Speech results after repair of the cleft soft palate. Plast Reconstr Surg 1995; 95:1150-54.
21. Chaudhuri PK, Bowen-Jones E. An otolorhinological study of children with cleft palates. J Laryngol Otol 1978; 92:29-31.
22. Weinfeld AB, Hollier LH, Spira M, Stal S. International trends in the treatmeant of cleft lip and palate. Clin Plast Surg 2005; 32:19-23.
23. Stephens P, Saunders P, Bingham R. Neonatal cleft lip repair: A retrospective review of anaesthetic complications. Paediatr Anaesth 1997; 7:33-36.
24. Dingman RO, Ricker L, Iob V. Blood loss in infant cleft lip and palate surgery. Plast Reconstr Surg 1949; 4:33-35.
25. Takemura H, Yasumoto K, TOI T, Hosoyamada A. Correlation of cleft type with incidence of perioperative respiratory complications in infants with cleft lip and palate. Paediatr Anaesth 2002; 12:585–88.
26. Mizushima A, Satoyoshi M. Preoperative assessment by common cold score in children. Rinsho Masui 1989; 13:28–34.
27. Gunawardana RH, Gunasekara SW, Weerasinghe JU. Anesthesia and surgery in pediatric patients with low hemoglobin values. Indian J Pediatr 1999; 66(4):523-6.
28. Olson RP, Stone A, Lubarsky D.The Prevalence and Significance of Low preoperative Hemoglobin in ASA 1 or 2 Outpatient Surgery Candidates. Anesth Analg 2005; 101:1337–40.
29. Meneghini L, Zadra N, Zannette G, Baiocchii M, Giusti F. The usefulness of routine preoperative laboratory tests for one day surgery in healthy children. Pediatr Anaesth 1998; 8:11-5.
30. Barcelona SL, Cote CJ, Thomson AA. Intraoperative pediatric blood transfusion therapy: a review of common issues. Part I: hematologic physiologic differences from adults; metabolic and infectious risks. Pediatr Anaesth 2005; 9:716-21.
31. Bell C, Rimar S, Barash P. Intraoperative ST-segment changes consistent with myocardial ischemia in the neonate: a report of three cases. Anaesth 1989; 71: 601–604.
32. Spritz RA. The genetics and epigenetics of orofacial clefts. Curr Opin Pediatr 2001; 13(6):556–60.
33. Tremlett M. Focus on: Paediatrics Anaesthesia for cleft lip and palate surgery. Current Anaesthesia & Critical Care 2004; 15: 309–316.