

# The Rule Of “10’s” in the Management of Unilateral Cleft Lip Children: The Komfo Anokye Teaching Hospital Experience

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## ABSTRACT

**Background:** Despite significant advances in cleft lip and palate (CLP) care, the often quoted “rule of 10 s” has not been objectively investigated concerning its practicality since its inception, especially, in low-resourced country like Ghana. **Aim of the Study:** This was to evaluate the unilateral cleft lip weight, haemoglobin and surgical repair outcome by considering the “Rule of 10’s”. **Materials and Methods:** A retrospective study of all consecutive patients who presented with unilateral cleft lip and were operated on during the period 2011 to 2015. The information retrieved from the patient’s records included the following at the time of surgery: Age (weeks), weight (pounds), hemoglobin level (g/dl), type of cleft and surgical outcome. **Results:** A total of 120 patients were seen during the study period (2011 to 2015) that had unilateral cleft lip. Female to male ratio was 3:2. (74) 62% had in addition, cleft palate (UCLp) and (46) 38% were only unilateral cleft lip without a palate (UCLo). Unilateral cleft lip was also divided into complete(UCLc) and incomplete unilateral cleft lip(UCLi). Out of the total number 120 patients seen during the study period, (80) 67% had complete unilateral cleft lip while (40) 33% had incomplete unilateral cleft lip. At week 10, the average weight were 11.2, 8.5, 8.2, 11.8 pounds for the various types of cleft at the time of surgery of the lip (UCLo, UCLp, UCLc and UCLi respectively).  $\geq 10$  weeks, the level of Haemoglobin at the time of surgery were 10.5, 8.6, 8.6 and 10.8 gm/dl (UCLo, UCLp, UCLc and UCLi respectively). Most of the patients, 28.4% with an associated cleft palate had their unilateral cleft repairs done by week 15. **Conclusion:** Children with unilateral cleft lip with an associated palate and unilateral complete cleft lip turned to have lower haemoglobin and weight at week ten after birth compared to unilateral incomplete cleft lip without cleft palate patients. This means that, the rule of 10s is still applicable in our centre especially for those with incomplete unilateral cleft lip without an associated cleft palate. There were more post-operative wound infections in children who had unilateral cleft lip with an associated cleft palate.

**Key words:** Cleft lip, unilateral, weight, hemoglobin, complication

## INTRODUCTION

Cleft lip and palate (CLP) are the most frequent congenital craniofacial deformities, with a mean prevalence of between 1:500 and 1:700 in Europe. It is estimated to

be 1: 1200 births in Sub-Saharan Africa.<sup>[1]</sup> CLP abnormalities vary greatly in terms of the width of the cleft and other characteristics. Treatment modalities also differ, depending on the timing of surgery and the technique of reconstruction.<sup>[2]</sup> For obvious reasons, the region where this deformity occurs

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(i.e., the face) is a very conspicuous part of the body. In the long term, the treatment of CLP should provide good aesthetic and functional (speech and occlusion) results.<sup>[3,4]</sup> One of the major problems in the treatment of CLP patients is that the definitive results of treatment are not visible until two decades after primary surgery. Because the patient’s physical development and level of cooperation may vary, the final outcome cannot be predicted when the treatment starts. In fact, the final result can be assessed only when the patient is about 20 years.<sup>[5]</sup>

CLP is often associated with decreased growth rate, which is likely to be secondary to children’s inability to feed appropriately.<sup>[6]</sup> According to the literature, children with either cleft lip or palate have a short, fast, uncoordinated, and ineffective intraoral suction, which may cause asphyxia, nasal regurgitation, and as excessive air ingestion.<sup>[7,8]</sup> In fact, studies showed that children with clefts have lower height and weight when compared to a control group, especially during the 1<sup>st</sup> year of life.<sup>[9,10]</sup>

Timing of CLP repair remains controversial in the literature.<sup>[8]</sup> A compromise must be reached between the age of the patient at surgery and the surgical outcome with respect to facial growth, scarring, speech and language development, and psychological factors.<sup>[10]</sup>

Although the timing of cleft lip repair is contingent on a number of factors, the “rule of 10 s” remains a frequently quoted safety benchmark. Initially reported by Wilhelmsen and Musgrave in 1966 and modified by Millard in 1976, Wilhelmsen and Musgrave<sup>[8]</sup> recommended that surgery should be delayed until the patient is 10 weeks, weighs at least 10 pounds, and had a hemoglobin (Hb) of at least 10 g/l and a white cell count of <10,000. He observed that, when these rules were followed, complications were 5 times less.<sup>[8]</sup> Despite significant advances in CLP care, the often quoted “rule of 10 s” has not been objectively investigated concerning its practicality since its inception, especially, in low-resourced countries like Ghana. There is the need to evaluate the surgical outcome taking into consideration the challenges we faced in the area of malaria, sickle cell diseases, and the lack of special care for CLP patients in most of our facilities.

It is important to continually validate and evaluate this rule as the field of CLP continues to advance and most, especially, to take into consideration the specific challenges faced by the different communities and health institutions around the world. This was to evaluate all consecutive unilateral cleft lip weight, haemoglobin and surgical repair outcome by considering the “Rule of 10’s”.

## MATERIALS AND METHODS

This was a retrospective study of all consecutive patients who presented with UCL and were operated on during the period 2011–2015. The information retrieved from the patient’s

records included the following at the time of surgery: Age (weeks), weight (pounds), Hb level (g/dl), type of cleft, and surgical outcome. The cleaned data were entered into SPSS II for descriptive analysis. Ethical clearance was obtained from the Kwame Nkrumah University of Science and Technology Research and Publication Committee.

## RESULTS

A total of 120 patients were seen during the study period who had UCL. Female-to-male ratio was 3:2. Age range was 10 weeks–45 weeks. The average age was 25.7 weeks. Some of the children who had UCL also had an associated cleft palate (CP) (Unilateral CLP [UCLP]). Further subdivision of the UCL showed the following: 74 (62%) cleft lip (unilateral) had, in addition, CP and 46 (38%) had only UCL. The UCL was also divided into complete and incomplete. Out of the total number, (80) 67% had complete unilateral cleft lip (UCLc) while (40) 33% had incomplete unilateral cleft lip (UCLi). The age ranges from 11 to 20 weeks (34%) was the highest respondents followed by ≥10 weeks (30%). The least recorded age range was 81 to 90 weeks (3 %). This means that, ages 0 to 20 weeks was 64 (53.3%) of the total population in this study.

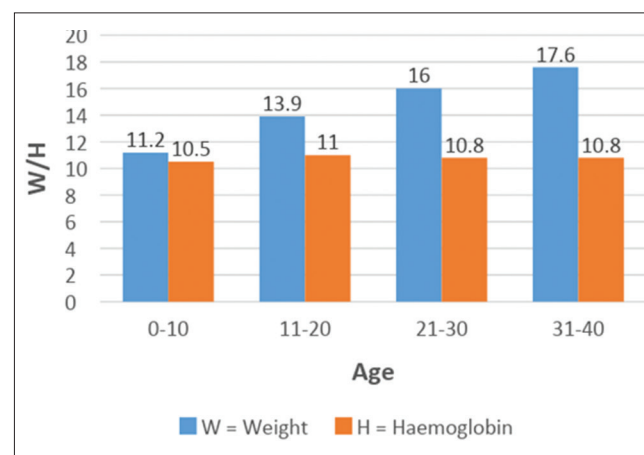


Figure 1: Unilateral cleft lip

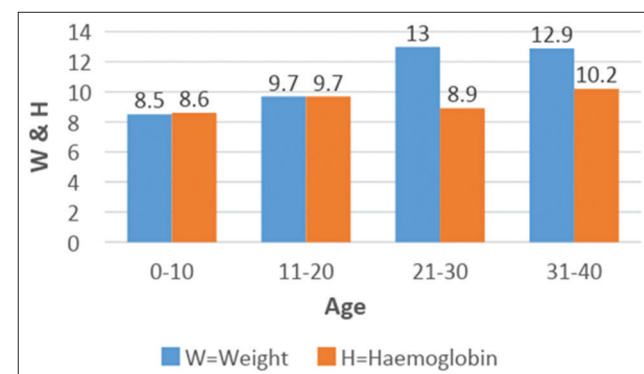


Figure 2: Combined unilateral cleft lip with palate cleft

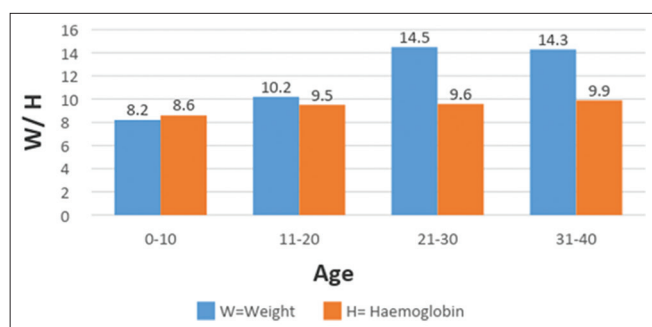


Figure 3: Complete unilateral cleft lip

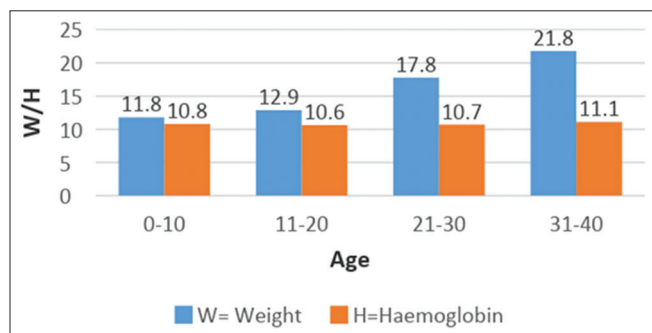


Figure 4: Incomplete unilateral cleft lip

### Compare weight (pounds) at the time of surgery

According to Figures 1, 2, 3, and 4, for age range  $\geq 10$  week, the average weight was 11.2, 8.5, 8.2, and 11.8 pounds for the various types of cleft at the time of surgery of the lip (UCL, UCLP, UCLc, and UCLi, respectively). For 11–20 weeks, the average weight for the various types of cleft was 13.9, 9.7, 10.2, and 12.9 lip (UCL, UCLP, UCLc, and UCLi, respectively). If we have to stick to the rule of 10s in the management of cleft lip, then the most appropriate time to repair cleft for UCLP will be between 11 and 20 weeks. Most of the patients, (21) 28.4%, with associated cleft palates had their unilateral cleft repairs done around week 15.

Below are figures for the various types of Unilateral cleft against their corresponding weights (W) and Haemoglobin (H) at the Age of surgery.

### Compare Hb at the time of surgery

Age ranges  $\geq 10$  weeks, the level of Haemoglobin at the time of surgery were 10.5, 8.6, 8.6 and 10.8 (UCL, UCLp, UCLc and UCLi respectively). Age range 11 to 20 weeks, the level of Haemoglobin were 11.0, 9.7, 9.5 and 10.6 (UCL, UCLp, UCLc and UCLi respectively). Again UCLp patients had a lower haemoglobin by the tenth week.

### Complications

All the complications were seen in UCLP and UCLi. According to Table 1, wound infections and hypertrophic scars were higher in patients who had their lips repaired at

Table 1: Post-operative complications according to the age of surgery

Age (weeks)	Wound infection	Hypertrophic score
0–10	10	8
11–20	2	5
21–30	2	4

week 10 (10 and 8, respectively). The frequency of infection and hypertrophic scars was lesser in those in the age range of 11–20 weeks.

## DISCUSSION

In sub-Saharan Africa, most cleft centres have adopted the ‘Rule of 10s’ in the management of their cleft lip patient and this include a Hemoglobin level of 10g/dl and a weight of 10 pounds and at least baby should be 10 weeks old. This rule has also been adopted by our center. The Rule ensures that patients are safe at the time of surgery. According to this study, the average weight for those with UCL was 11.2 pounds at 10 weeks during the time of surgery. However, those with UCLP at the time of surgery in 10 weeks had an average of 8.5 pounds. This means that, if we use the rule of 10s for the repair of cleft lip, then it is likely that those with UCLP would not have attained the required 10 pounds at 10 weeks. In this study, repairs done after week 10 were closer to 10 pounds. From the above analysis, it can be argued that it was ideal to surgically repair UCLa at week 10. However, for patient with UCLP, it was good to do the repair between 11 and 20 weeks. The Hb levels were also adequate for the UCLP after week 10.

The differences in weight and Hb could be attributed to the fact that those with UCLP have difficulty in feeding, especially, sucking breast milk. This may sometimes force some mothers not to stick to exclusive breastfeeding which then can lead to diarrhea if proper hygiene is not followed as has been the case with some of our patients. Our environment is in malarial endemic zone. This means that, if feeding is not adequate, then they may have less resistance to fight malaria and other infections leading to the low weight and Hb levels. Our center does not have adequate feeding support for the patients outside the teaching hospitals. This means that most mothers have to express the breast milk into a feeding cup, and since sometimes the food might not be adequate, supplementation with formula and local food is done. This possible complication can lead to dehydration and subsequently lead to difficulty in weight gain.

It was also noted in this study that those with UCLc tend to have a higher Hb level and weight at the time of week 10 compared to those with UCLi. This finding may be

because UCLi possesses less feeding challenges and again the defect is not too embarrassing for the parents. Mothers are less psychologically traumatized and were more encouraged to spend extra time to feed their babies. From Table 1, discussed earlier, it was evident that, between 11 and 20 weeks, most of the patients had adequate Hb and weight at the time of surgery. This may explain why there were fewer complications with this age group. In this study, it was noted that most of the complications were associated with UCLP and UCLi when the repair was done at week 10. There is more surgical manipulation of the soft tissue in UCLi than UCLc, and this may explain why there were more wound infection and hypertrophic scarring among the UCLi cases.

It is well documented that children with CP weigh less than regular children during their 1<sup>st</sup> month of life. At the end of the 1<sup>st</sup> year, weight gain is similar comparing normal and affected children. However, factors that optimized weight gain included choosing the best treatment for each case, proper guidance, and multiprofessional integrated care.<sup>[6]</sup> In a study in Nigeria, it was concluded that only 4.9% of patients who had UCL surgery were transfused as compared with 50% for CLP surgery.<sup>[2]</sup> This may imply that, if we really want to repair UCLP at week 10, then we should be prepared to transfuse our patient which is currently not the case in our center. Worldwide, cleft lip surgery is a low volume blood loss surgery.<sup>[5]</sup>

## CONCLUSION

Children with unilateral cleft lip with an associated palate and unilateral complete cleft lip turned to have lower haemoglobin and weight at week ten after birth compared to unilateral incomplete cleft lip without cleft palate patients. This means that, the Rule of 10s is still applicable in our centre especially for those with incomplete unilateral cleft lip without an associated cleft palate. Patients with complete unilateral cleft lip and those with an associated cleft palate hardly attain the required weight and hemoglobin at week 10.

There were more post-operative wound infections in children who had unilateral cleft lip with an associated cleft palate

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