

## Research Article

### THE RED CODE. A New Concept in the Prevention of Post-Surgery Bleeding of the Cleft Patient. A Multicentric Study.

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#### Abstract

**Introduction:** Bleeding, during post-operative period is not only frustrating for the surgeon but may also lead to life threatening condition for the patient. Sometimes if uncontrolled or not managed adequately can lead to death of patient. It's a worldwide problem as evident with articles from all over the world, especially dangerous in pediatric patients and more specifically cleft surgery patient post operatively.

**Objective:** The objective of the study was to determine an algorithm which can help in the management and prevention of postoperative bleeding cleft patients.

**Methods:** This paper presents the Red Code Algorithm, for pre, intra and postoperative management of cleft patients. The study was performed in different centers of Smile Train Foundation in Ecuador, Peru, Paraguay, Nicaragua and Morocco.

**Results:** We studied 864 primary and secondary cleft lip and palate surgeries, performed during one year by the same group of surgeons. In these 864 consecutive cases the Red Code Algorithm was applied. Forty-five patients (5.3%) presented more bleeding compared to the average of patients, and 2 cases (0.23%) required surgical re-intervention for hemostasis control. The control group had a total of 1243 patients, who had surgery by the same team before the introduction of the Red Code Algorithm. Of them, 113 cases (9.1%) presented more bleeding compared to the average, and 37 cases (2.97%) required surgical re-intervention to achieve hemostasis control.

**Conclusion:** This approach reduced the incidence of postoperative bleeding in all types of cleft surgeries.

**Keywords** | Red Code, Bleeding, Cleft surgery

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#### Introduction

Bleeding during post-operative period is not only frustrating for the surgeon but may also lead to life threatening condition for the patient. He may even do revision surgery immediately to control the bleeding, which can be difficult to stop. Sometimes if uncontrolled or not managed adequately can lead to death of patient. It's a worldwide problem as evident with articles from all over the world, especially dan-

gerous in pediatric patients and more specifically cleft surgery patient post operatively.<sup>1</sup>

Another aspect is cost of treatment of patients. It increases many a fold due to not only the demand of medical personnel's but also the operation theater items, gases and disposables

Many studies have been done previously in this aspect but not many specifically for cleft lip and palate

patients. In Levy's studies on cardiac surgery,<sup>6,8</sup> it was determined that about 4.7% of their cases needed re-exploration because of bleeding. In Jerrold study on trauma and orthopedics, percentage decreased to 1.9% as comparison to Levy's (RR, 0.44, 95% CI, 0.22 to 0.90), after applying their red code which also decreased morbidity and mortality.<sup>8</sup>

Reviews on cleft surgeries reveal that about 13% of them, presented an abnormal bleeding, and about 4.8% needed re-intervention to control hemostasis.

Experience has taught us that in most cases, "normal" postoperative bleeding stops after applying digital pressure for few minutes but sometimes due to any circumstance the bleeding restarts hours after the end of the surgery. This situation may lead to a late diagnosis and re-intervention with possible complications. On the other hand, the opposite situation may also occur: the patient may be rushed into the operative room to review bleeding under general anesthesia, and once the patient is intubated no further bleeding appears. Sometimes the bleeding is tried to be controlled with pharmacological drugs as evidenced with Levy's studies.<sup>8</sup> This shows us that we don't have a clear algorithm that allows us to decide either re-intervention without loss of time (negative false), or discharge positive false. So, this study is done to determine an algorithm which can be applied to the pediatric patients of primary and secondary cleft lip and palate internationally for the better management in regard to the patient care.

## Methods

It is a multicentric study performed from January 2019 to December 2019 for a period of one year in Ecuador, Peru, Paraguay, Nicaragua and Morocco, within each country Operation Smile Foundation and with the respective knowledge and approval of the corresponding medical directors, the Red Code, described below, was routinely applied for the prevention of postoperative bleeding in primary and secondary cleft lip and palate patients. 864 patients were included in the study and surgeries were performed by same group of surgeons. The results were compared with those from the same countries, from a period of three years, when the Red Code Algorithm was not yet applied. Following are the operational definitions.

### Hemostatic Safety Bleeding (HSB)

For a "predictor" to know which volume of blood loss in a cleft surgery could leave the patient without enough coagulation factors, that the patient would need in the postoperative period if a major bleeding appeared. So, with this "predictor" we could define measures to control the loss of coagulation factors, and unnecessary transfusions, and revisions.<sup>4</sup>

Our study was able to define that cleft surgeries in patients whose intra-operative bleeding volume reached 10% of their total volume, needed the use of preventive measures, such as pro-coagulant medication, and others to avoid immediate surgical reviews and even blood products transfusions.

In our study we have adopted this value of 10% of the calculated total blood volume of each patient based on the HSI or Hemostatic Safety Index which, once reached, activates the Cleft Patient Surgery "RED CODE", setting in motion mechanisms focused on saving intraoperative coagulation factors, and eliminating false positives that confuse the diagnosis of persistent bleeding in the postoperative period.

### Permitted Bleeding

This is the index that indicates the maximum amount of blood that a patient can lose until he reaches a minimum tolerable total blood volume. Once this value is exceeded the patient will need measures of blood replacement according to protocols; the Anesthesia Mexican Association has developed a calculator which, in an elective surgery, generally represents a value close to 20% of the patient calculated total blood volume.<sup>5</sup>

### Alpha- and Beta-Adrenergic effect

Epinephrine acts in both  $\alpha$  and  $\beta$  receptors causing vasoconstriction and vasodilation respectively. At high circulating concentrations  $\alpha$  receptors cause vasoconstriction, an effect that is predominant for the first hour overcoming the beta effect. In the second hour, the low circulating levels of epinephrine produce stimulation of  $\beta$  receptors. It produces therefore general vasodilatation from the second hour until its effects disappear at the third hour.<sup>11</sup>

### Tranexamic acid

Tranexamic acid is an active hemostatic agent which can be administered orally and parenterally. It has

effects similar to those of aminocaproic acid, but it is about 10 times more potent as an inhibitor of plasminogen activation, reducing the dissolution of hemostatic fibrin by plasmin.

After an administration of 1300 mg of tranexamic acid, the maximum plasma concentrations are reached after 3 hours. Absolute oral bioavailability is approximately 45%. A decrease in plasma levels is observed according to a triexponential equation, with a half-life of elimination of about two hours. After intravenous administration of 10 mg / kg, approximately 90% of the dose is eliminated in about 24 hours.<sup>11</sup>

In general, 1.4% of the patients presented adverse reactions such as nausea and vomiting, diarrhea, hypotension, dizziness, visual abnormalities and alterations of the retina. Venous and arterial thrombosis and thromboembolism have also been reported, as well as obstructions of the retinal artery and vein. Urethral obstructions have also been described occasionally due to formation of clots in patients with upper urinary tract hemorrhage.

### **Aminocaproic acid**

Aminocaproic acid belongs to a class of medications called pro-hemostatic. It works by slowing the disintegration of blood clots. (MedlinePlus, 2010). It is used to control bleeding that occurs when blood clots dissolve too quickly. This type of bleeding can occur during or after surgery of the heart or liver, in people with certain bleeding disorders; in people with prostate, lung, stomach or cervix cancer and in pregnant women with abruptio placentae. Aminocaproic acid should not be used to treat bleeding that is not caused by rapid disintegration of a blood clot.<sup>11</sup>

### **Red Code Algorithm**

It is important to understand that not all surgeries have the same bleeding risk, for example the palate surgery is riskier due to vascularization, which is very rich. The lip repair has minor risk but it exists.

The bleeding prevention in cleft surgery will begin in the preoperative, and continue in intraoperative and postoperative phases.

### **Preoperative Phase**

It consists of integral clinical evaluation to assess the presence of patients with bleeding risk. In this phase it

is imperative the role of:

**The Pediatrician.** – They must specify clinical conditions involving coagulation disorders such as Von Willebrand disease, mild hemophilia A, congenital disorders of platelet function: Bernard Soulier syndrome, vascular disorders: Ehler Danlos, Marfan syndrome, Wilms tumor, myelin and lymphoproliferative diseases, hypothyroidism, congenital heart disease.

**The Anesthesiologist.** - They will determine the Permitted Bleeding value of the patient, according to weight, the real hematocrit and the minimum value the patient can reach. This value is usually around 20% of the total blood volume. The Hemostatic Safety Bleeding value will be around 10% of this volume.

They will also determine as usual other parameters of importance relating to airway manage and difficult airway patient.

**The Cleft Surgeon** – In this phase, they will evaluate the extent, complexity, and the possible bloody areas of the surgery.

### **Intraoperative Phase**

In this phase the whole teams work together to evaluate the intra-operative bleeding.

**Auxiliary Nurse:-** In order to assess the exact amount of blood loss, the Auxiliary Nurse will quantify the amount of blood collected in the suction container (having previously verified it was empty at the beginning of the surgical procedure) and in the gauzes and compresses used (counting them, knowing that one completely wet gauze contains 10cc of blood). They will also quantify the saline used for surgical irrigation when considering the liquid collected in the suction container. In case the blood loss exceeds the previously defined HSB value (Hemostatic Safety Bleeding value) for that patient, the “Red Code” will be activated.

In order to quantify how much blood is contained in a gauze or compress, we have carried out field tests to define that value. We concluded that each square centimeter of gauze with four layers is impregnated with one gram of blood. (Fig. 1)



**Fig. (1)** *Blood Soaked Gauze Weighted on the Scale*  
Also, each square centimeter of gauze is impregnated with one cubic centimeter of blood (Fig. 2)



**Fig. (2)** *Each Gauze Placed on a Sheet and Impregnated Blood Measured*



**Fig. (3)** *Total Number of Soaked Gauzes*

**Scrub Nurse.** - They must quantify the saline solution used during the surgery, and must also count the number of gauzes used (completely wet gauzes, as shown in (Fig. 3) in order to eventually determine the intra-operative blood loss. If the value exceeds the patient HSB, the RED CODE will be activated, and adequate treatment started according to our Red Code Algorithm.

**Photographer-** Photographic records of the cases will be examined. The purpose is to document the bleeding through pictures (the gauzes used and the blood collected in the suction container, and any other measure taken (flushing of the surgical field, bloody gastric content...)

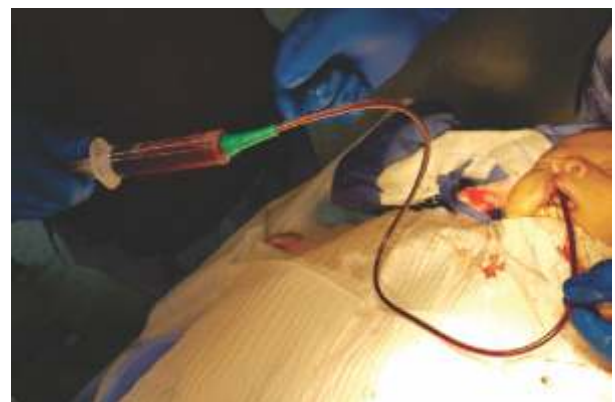
**Anesthesiology, Pediatrics, Nursing-** Once the Red Code has been activated intra-operatively, the reasons for the bleeding shall be verified for quantification of that bleeding (recount of gauzes, suctioned blood, etc.) for definitive quantification.

**Medication shall be initiated as indicated in the Red Code Algorithm:** Dexamethasone, Tranexamic Acid and Ondansetron. Antibiotics in therapeutic dose should also be initiated.

Quantification of the bleeding will continue until the end of the surgery

**Cleft Surgeon-** The surgical team leader might assist the surgeon performing the surgery in assessing the case, identifying the reasons for the bleeding and controlling it. They will follow the Red Code Algorithm.

At the end of the surgery, the surgeon should flush with saline the oral and nasal cavity to remove the clots, and aspirate the pharynx and gastric contents (Fig. 4). If this procedure is not done, it could mislead us, because it might be from previous intra-operative bleeding or be new.



**Fig. (4)** *Pharyngeal and Gastric Contents being Aspirated*

If the bleeding was not adequately controlled, a palatal pack will be secured and left in place during the next six hours and a nasopharyngeal catheter will be placed to facilitate oxygenation (Fig. 5)



**Fig. (5)** Nasopharyngeal Catheter Secured after Palatal Pack Placement

The surgeon in charge of any children with severe

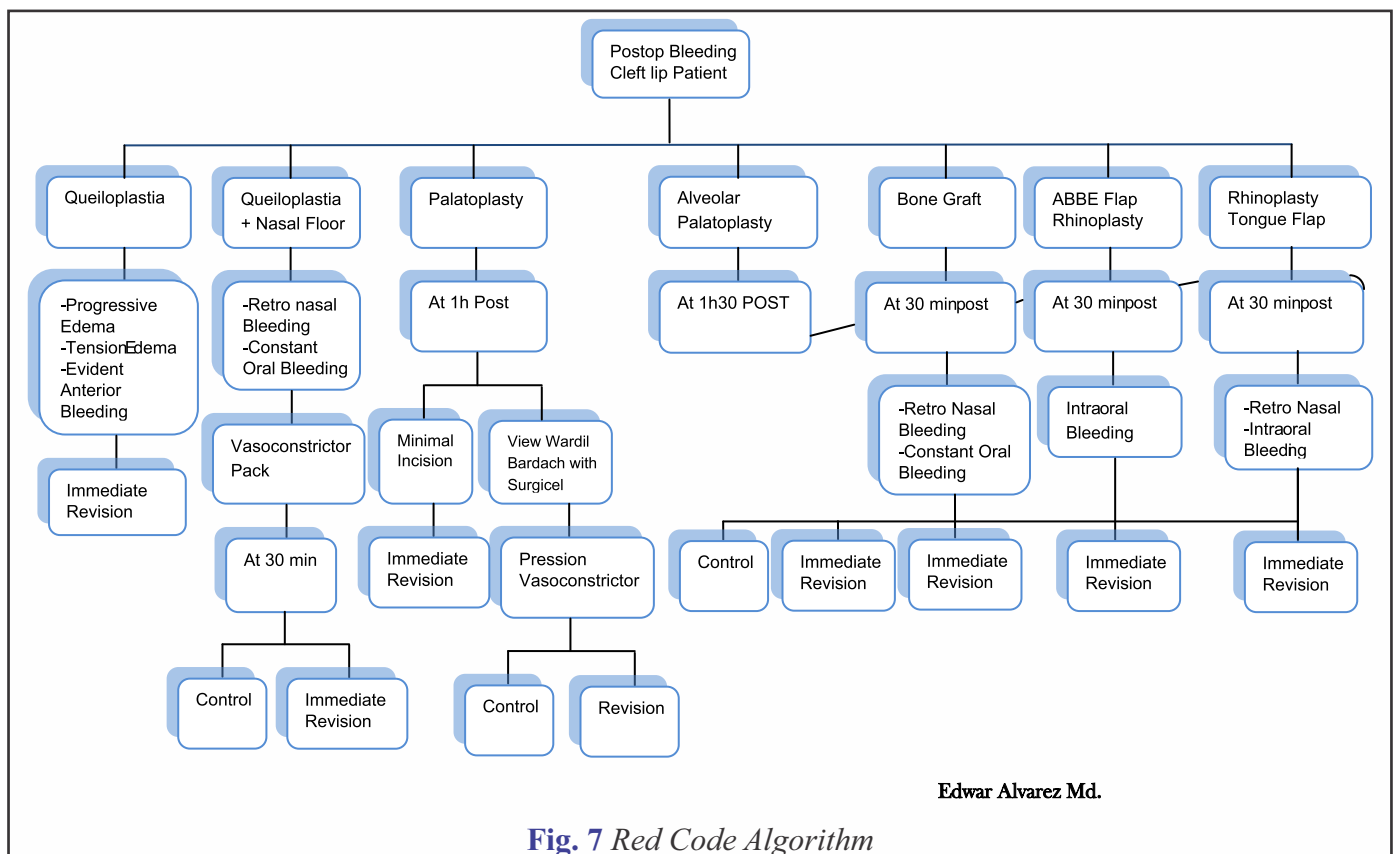
bleeding should anticipate anterior coagulopathy due to coagulation factors consume because of that bleeding. They should therefore focus their efforts on achieving hemostasis as quickly as possible. Early intervention should be done to prevent the consequences of hemorrhagic shock: hypothermia, acidosis and hemodilution.<sup>(12)</sup>



**Fig. (6)** Recovery area for post-operative patients

**Postoperative Phase**

Once the surgery is concluded and under the conditions previously mentioned, the patient will be taken to a predetermined place in the recovery area (Fig. 6)



**Fig. 7 Red Code Algorithm**

where the personnel, that is nurses, emergency doctor or intensive pediatrician will be in charge for immediate postoperative management.

In this area there will be a scheme with diagnostic and therapeutic suggestions (Red Code Algorithm). (Fig. 7)

When the patient is in hospitalization and has stayed six hours without any incident, the Red Code is suspended; at that moment the patient will receive the last dose of Antifibrinolytics.

## Results

We studied 864 primary and secondary cleft lip and palate surgeries, performed during one year by the same group of surgeons. In these 864 consecutive cases the Red Code Algorithm was applied. Thirty-five patients (5.3%) presented more bleeding compared to the average of patients, and 2 cases (0.23%) required surgical re-intervention.

The control group had a total of 1243 patients, who had surgery by the same team before the introduction of the Red Code Algorithm. Of them, 113 cases (9.1%) presented more bleeding compared to the average, and 37 cases (2.97%) required surgical re-intervention to achieve hemostasis control.

Being a case-control study, it is correct to obtain the Odds Ratio estimate to demonstrate, statistically, the association between the possibility of postoperative bleeding in these patients by not applying the RED CODE with its respective protocol. The following table (Table: 1) of 2X2 and the mathematical determination of the Odds Ratio are presented:

	Post Surgical Bleeding	No Bleeding
No Red Code	37	1130
Red Code Applied	2	862

$$OR = \frac{a/b}{c/d}$$

$$OR = 0.032 / 0.0023$$

$$OR = 13.9$$

Meaning; there are 13.9 times more likely to present post-surgical bleeding when the red code is not applied

## Discussion

Bleeding is considered as a major problem in cleft

surgeries especially in cleft palate. And because of this reason the patients are kept in ICU for the immediate post-operative period for 6 hours up to 1 day.

Surgically reviewing a cleft lip and palate patient in the immediate postoperative period has a high morbidity, whether determined by an early diagnosis (false positive), but also in those where a late decision was taken (false negative).

Administering antifibrinolytic therapy to all patients to avoid this complication has also risks. There is no scientific evidence to support it. This medication has also important undesirable effects.

In our study, we found that activating the Red Code in those patients who bled above the HSB value was effective. It allowed us to choose those patients who would need additional procoagulant and supportive measures. We implemented the measures described in our Algorithm.

Our study showed a reduction in review surgeries from 2.97% in our control group to 0.23% in our Red Code Algorithm group.

Our next goal is to implement this Red Code Algorithm in other centers and in from different countries, in order to study its applicability and reproducibility, and improve or even adjust or modify it. Also we need more patients for statistically significant and consistent conclusions.

## Conclusions

From the results obtained in this study we conclude that blood transfusion prevention protocols applicable in complex surgeries, such as scoliosis, cardiac and craniosynostosis, are also applicable in cleft surgery, with the same validity.

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