Abstract:
Background: India has an estimated backlog of 1000000 cleft patients. A total of 35000 new cleft patients are born each year. With the capacity to operate on approximately 50000 patients each year only 15000 patients from the national backlog can be operated upon each year if capability is not augmented. Objectives: To reach the population at large we meticulously planned an out-reach programme and operated on patients even in rural set ups with lack of modern facilities. We operated on patients at sub divisional centres, where apparatus for providing sevoflurane was not available. Institutional Ethical clearance was taken before conduction of the study. Patients who required prolonged surgery were taken to the tertiary centre. Working ventilators were also not available at peripheral centres. Materials and Methods: This interventional study was carried in a time span of four years on nineteen hundred and nine patients, after taking approval from the Institutional Ethical Committee. Patients were screened and some were operated at rural centers and others at a tertiary care centre. Patients who could not afford to come to the tertiary care centre were operated at different rural centers. Informed consent was taken. Results: There were 1909 patients with Congenital Facial Anomalies (CFA) over four years period out of which 918 patients were of either unilateral or bilateral cleft lip. They were successfully operated at rural health centers with limited facilities. This could reduce the total load of surgeries for CFA at tertiary care hospital ensuring safe surgeries for all with CFA for all age groups and both genders. No mortality was recorded and post operative complications consisted of nausea and vomiting, three had delayed recovery and one had laryngospasm. Conclusion: Outreach programmes can increase the efficacy of Smile Train Project and effective screening of patients before surgery can result in fruitful outcomes even in a rural set up with lack of modern anaesthetic facilities.

Keywords: Congenital Facial Anomalies, Management in Rural Set Up

Introduction:
India has an estimated population of one million untreated cleft patients. Facilities for its treatment are limited and unevenly distributed. The Smile Train Project with its focus on cleft patients started its activities in India in 2000 [1, 2]. It made surgeons performing cleft lip and palate surgeries equal partners (equal contributors) in this programme and helped them to treat as many patients with cleft lip and palate as possible. In the last 9 years, more than 200000 cleft patients received free treatment in Smile Train partner hospitals in India. India has an estimated backlog of 1000000 cleft patients. A total of 35000 new cleft patients are born each year. With the capacity to operate on approximately 50 000 patients each year, only 15000 patients from the national backlog can be operated upon each year. If capability is not augmented; it will take about 100
years to clear our present backlog [1-6]. However, if we could increase our capacity by twofold, the backlog shall be cleared in a decade. Such an attempt was made by Singh SK et al in 2009[1] and the project proved to be a great success. In the present socio-economic condition, even the informed family having children with cleft lip and palate cannot afford to seek care at the nearest centre. Most of such families have many children to be looked after by the working mothers. In some cases a trip to the hospital takes more than 7 days. Even a few days off work is not sustainable for the family [1, 2, 6]. A programme that merely provides infrastructure and facility for cleft surgery but lacks other components (like transportation cost for patients, compensation for loss of wages for parents, follow up costs, nutritional supplements for the children etc) will be a failure in the socio-economic realities of our country.

Cleft lip and palate is one of the most common craniofacial anomalies. The surgery is not performed usually until the baby is three months of age. The anaesthesia technique is dependent on the difficulty of the airway. The anaesthesiologist therefore requires knowledge of the pediatric airway and of this particular anomaly and skill in the thorough preparation of the equipment used for intubating a baby for this procedure [4-6].

To reach the population at large, we meticulously planned our out-reach programme and operated on patients even in rural set ups with lack of modern facilities but with no compromise in patient care, i.e. the patients were not exposed to any additional risk. We operated on patients at sub divisional centres, where apparatus for providing sevoflurane was not available. Patients who required prolonged surgery were taken to the tertiary centre. Working ventilators were also not available at the peripheral centres. We only operated the cases which were less difficult and kept ready at hand ambulances for transferring the patients if required from peripheral centre to the tertiary centre.

**Material and Methods:**
This interventional study was carried out in a time span of 4 years in between September 2008 to October 2012 under guidance of a tertiary care hospital in West Bengal. After taking approval from the Institutional Ethics Committee health camps were organized. Patients were screened and selected cases were operated at rural centers and others at a tertiary care centre. A total of nineteen hundred and nine patients of American Society of Anaesthesiologists (ASA) as per grade I and II aged 6 months or more of either sex were enrolled [6]. Patients who could not afford to come to the tertiary care centre were operated at different rural centers. We arranged for camps at sub divisional centres and operated patients there with the same team of anaesthetists and surgeons. This was a part of the smile train project, so doctors who had participated in the project could only operate. Post operative care was provided by local doctors and pre anaesthetic check up was also done by them. These doctors were qualified young anesthesiologists and surgeons working in government hospitals. Patients who had to undergo prolonged surgeries were not operated in those centres. 4 rural centres were used. They were situated within 60 kilometers from the tertiary centre. Study of cleft lip surgery indicated that it was a suitable surgery to be undertaken even when apparatus for providing sevoflurane or ventilators were not available. Even then ambulance was always kept ready at hand with emergency drugs and equipments, for any complications, so that the patient could be shifted to the tertiary centre as and when required. Beds in Intensive care units and ventilators were kept ready on the day of surgery at the tertiary centres in anticipation of complications that may arise during anaesthesia or surgery at the peripheral centres. Six hundred and ninety patients were operated at these peripheral centres. Informed and written consent was taken.
Inclusion criteria:
A total of nineteen hundred and nine patients of ASA grade I and II aged 6 months or more of either sex.

Exclusion criteria:
Patients who were suffering from any other congenital syndromes associated with cleft lip and palate abnormalities. Preoperative evaluation was done with main focus on upper airway anomalies, anemia, upper respiratory tract/chest infection, and other associated congenital anomalies of cardiovascular system.

All operations were done by qualified experienced plastic surgeons and anaesthesia was administered by competent experienced anesthesiologists.

Routine blood and urine tests were done. X-rays chest and lateral view of neck were evaluated for chest disease and/or difficult airway. Instructions for preoperative fasting were given as per Oral guidelines [6].

General anesthesia for operative procedures at the tertiary care hospital:
Preoperatively, standard monitors for heart rate, blood pressure, temperature, ECG and SpO2 with EtCO2 probe were attached, and intravenous fluid (Ringer lactate) was started. A stethoscope was used to monitor heart sounds and respiratory sounds, and warming blanket was used to avoid hypothermia. The patients were premedicated with glycopyrrolate (0.01 mg/kg). After preoxygenation for 3 minutes, sevoflurane induction was safely performed in the infants, followed by intubation. Intravenous induction with, ketamine and midazolam was done for older patients. Laryngoscopy and intubation was facilitated with succinylcholine. Oral endotracheal intubation was performed with south-pole RAE (Ring-Adair-Elwyn) endotracheal tube of appropriate size. After confirming proper positioning of endotracheal tube, it was taped below the lower lip in the midline. The pharyngeal packing with moistened ribbon gauze was done to absorb blood and secretion. Bilateral air entry was reconfirmed after proper positioning of head in extension. Eyes were lubricated and protected. After gag and pack insertion, ventilation was reassessed. Anesthesia was maintained with sevoflurane and nitrous oxide 60% in oxygen with atracurium 0.5 mg/kg. The patients were mechanically ventilated with adequate minute ventilation to maintain normocapnia. Parenteral fentanyl was used when required. In order to reduce blood loss and improve the surgical field, 2% xylocaine with adrenaline was used. Blood transfusion was not needed in any of the cases. Infraorbital nerve block was performed in selected cases of cleft lip and nasopalatine and palatine nerve block, for palatal surgery, by 0.25% bupivacaine for postoperative analgesia.

After completion of surgery, oral suction was done followed by pharyngeal pack removal. Residual neuromuscular blockade was reversed with neostigmine and glycopyrrolate. Extubation was done after return of consciousness, spontaneous respiration of adequate tidal volume and protective reflexes. Tongue suture was placed after palate surgery to allow forward retraction of tongue to prevent potential postoperative airway obstruction [4-6].

Postoperatively, the patients were nursed in lateral position to optimize air movement and minimize chances of aspiration. The monitoring for bleeding, vomiting or airway obstruction was done. Additional analgesia with diclofenac suppositories was used.

General anesthesia for operative procedures at the rural centers:
Ketamine and ether was used instead of sevoflurane in the rural set up and all other procedures followed were same. No complication occurred during the postoperative period except a few patients had nausea and vomiting (2%), who were managed with antiemetics. None of the
patients required blood transfusion. Patients recovered well after surgery. Cost of anaesthesia were compared between the different centers using T- test and P- value< 0.05 was considered as significant.

Results:
There were 1909 patients with Congenital Facial Anomalies (CFA) over four years period out of which 918 patients were of either unilateral or bilateral cleft lip. They were successfully operated at rural health centers with limited facilities. No mortality was recorded and post operative complications consisted of nausea and vomiting, on occasional patient had delayed recovery and one had laryngospasm.

There were 788(41.27%) females and 1121 (58.72%) males. Age wise grouping is given in Table 1. Of 1909 patients 664(35%) patients presented below the age of 2 years (Table 1).

Table 1 shows gender wise distribution of unilateral and bilateral cleft lip patients.

Table 3 shows sex wise distribution of subjects operated in tertiary centre other than cleft lip.

Significant difference in cost of anaesthetic medicines was seen between the rural and urban centres (Table 4). Six hundred and ninety patients of cleft lip surgery were operated at the rural centre. All other cases were operated at the tertiary centre.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Infants</th>
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<th>Above 5 to 20 years</th>
<th>Above 20 years</th>
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<tbody>
<tr>
<td>Number of subjects in each group</td>
<td>446</td>
<td>218</td>
<td>290</td>
<td>731</td>
<td>224</td>
</tr>
<tr>
<td>Percentage of subjects</td>
<td>23.36% (446/1909)</td>
<td>11.42% (218/1909)</td>
<td>15.19% (290/1909)</td>
<td>38.29% (731/1909)</td>
<td>11.73% (224/1909)</td>
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</table>

<table>
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<tr>
<th>Parameters</th>
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<th>Parameters</th>
<th>Primary Bilateral Cleft Lip (N=141)</th>
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<tbody>
<tr>
<td></td>
<td>TC*</td>
<td>RC **</td>
<td>TC*</td>
</tr>
<tr>
<td>Females (375)</td>
<td>75 (20%)</td>
<td>300 (80%)</td>
<td>Females (49)</td>
</tr>
<tr>
<td>Males (402)</td>
<td>82 (20.3%)</td>
<td>320 (79.6%)</td>
<td>Males (92)</td>
</tr>
<tr>
<td>Total</td>
<td>20.20% (157/777)</td>
<td>79.79% (620/777)</td>
<td>Total</td>
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</tbody>
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*TC- Tertiary centre, **RC- Rural centre
Discussion:
Cleft lip and palate are the commonest congenital deformities. There is associated facial disfigurement causes feeding, speech and dental development problems and has significant psychosocial consequences [2, 6]. Surgery aims to restore form and function and modern techniques can make many defects undetectable. Airway management problems, dealing with associated abnormalities and young age of patients all present as anaesthetic challenges [2-7]. The present study was conducted in a time span of four years, with no mortality and post operative complications were minimal. No blood transfusion was required in any case. The post operative complications consisted of nausea and vomiting (2% cases), 3 patients had a delayed recovery and one had laryngospasm.

An observational study was conducted by Qureshi FA et al in 2009 [8] on 172 patients of Smile Train project undergoing general anesthesia for cleft lip and palate repair in Peshawar. Out of 172 patients, in the age range of 6 months to 25 years, five patients developed hypothermia, two patients had...
difficult intubation, one patient had post operative pulmonary edema, one patient had respiratory depression and one patient developed postoperative significant bleeding requiring reexploration the next day. There was no death. None of the patient received intraoperative blood transfusion. Total of 99 procedures were undertaken in patients with cleft lip (unilateral & bilateral). A total of 58 procedures were undertaken for cleft palate. Remaining 15 were secondary cleft procedures. We had no anaesthetic complications following surgery, or during operation as we had taken adequate measures to prevent complications beforehand. Preanaesthetic check up was carried out meticulously and patients were screened. Patients in whom prolonged surgery and complications were anticipated were shifted to the tertiary centre. Subjects having respiratory tract infections were treated first and surgery was postponed till they were fit.

Kwari et al in 2010 [9] conducted a study of cleft lip and palate patients at University of Maiduguri Teaching Hospital and Federal Medical Centre Nguru both in north eastern Nigeria from January to June 2009. One hundred and six cleft patients presented for surgical repair under general or local anaesthesia. Fifteen (14%) patients all of whom were children, were unfit for general anaesthesia due to various medical reasons. Ninety-one (86%) cleft patients comprising 53 (50%) children and 38 (36%) adults had cleft repair under halothane general endotracheal anaesthesia and local anaesthesia, respectively. There was no anaesthetic complications recorded under local anaesthesia. Fifteen percent of children who received general endotracheal anaesthesia suffered various anaesthetic complications which included hypoxia (3.8%), laryngospasm (1.9%), kinking of endotracheal tube (5.7%), inadvertent extubation (1.9%) and pulmonary aspiration (1.9%). There was no mortality or anaesthesia-related morbidity at the time of discharge in all the cases. We also recorded no mortality or anaesthesia-related morbidity in our cases.

A study was conducted in India by Gupta K et al in 2010 [6] on 241 patients of cleft deformities, of both sexes, from infancy to adulthood. 27% of children less than 2 years underwent corrective surgery. The infants were anemic and undernourished. In our study 35% (664) of the patients presented below the age of 2 years as we had planned outreach programmes and operated even in rural set ups.
We had to use ether in our rural centres. Ether (diethyl ether) is an inhalational general anaesthetic agent listed in the 2004 WHO Model Formulary for induction and maintenance of general anaesthesia in adults and children. It is a potent anaesthetic that made modern surgery possible. A second and related product listed in the Formulary is the halogenated anaesthetic halothane. This is more stable and safer to use than ether, and offers more precise control over the anaesthetic state. Ether is an effective inhalational general anaesthetic, but its many disadvantages make it less suitable than halothane in most settings. However, ether continued to be listed in the WHO Model List of Essential Medicines because of its low cost and relative safety in inexperienced hands [10, 11]. It has a particular place in patients in whom halothane is contraindicated. Sevoflurane and halothane were not available in the rural areas and the cost of anaesthesia was also significantly decreased due to use of ether and this is of immense importance in a developing country like India. The anaesthesiologists in the rural set up were relatively inexperienced. The anaesthesiologists were qualified but they were young, so they had relatively less experience. The team from the tertiary centre was always present during the operative procedures to help them to manage complex problems like airway difficulties if they arose and use of ether added advantages.

**Conclusion:**
Outreach programmes can increase the efficacy of smile train project and effective screening of patients before surgery can result in fruitful and satisfactory outcomes even in a rural centre with lack of modern anaesthetic facilities.

**References**


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