ORIGINAL ARTICLE

Using low level laser therapy to reduce early postoperative airway obstruction following modified Hogan’s flap

Abdelrahman E. Ezzat a,*, Hanna M. EL-Shenawy b, Marwa M. El-Begermy c, Mustafa I. Eid a, Ayman Y. Abbas a

a ENT Department, Faculty of Medicine, Al-Azhar University, Cairo, Egypt
b Oral Surgery and Medicine Department, Orodontal Division, National Research Center, Giza, Egypt
c ENT Department, Faculty of Medicine, Ain Shams University, Cairo, Egypt

Received 23 October 2015; accepted 21 January 2016
Available online 13 April 2016

Keywords
Low level laser therapy; Biostimulation laser; Superiorly based (pharyngeal) flap; Obstructive sleep apnoea

Abstract
Introduction and objective: The most common postoperative complications of velopharyngeal insufficiency surgery are postoperative bleeding and airway obstruction or obstructive sleep apnoea. Consequently, the aim of this study was to evaluate the effect of low level laser therapy (LLLT) during the first postoperative days in children undergoing superiorly based pharyngeal flap (SBF) surgery.

Materials and methods: A randomized double blind clinical study on 30 children divided on two groups 15 patients each, who underwent SBF. LLLT was used in a group and the other was a control group. The study was conducted in academic tertiary care medical centres between 2013 and 2015. The degree of edema, oxygen saturation, occurrence of obstructive sleep apnoea (OSA) and steroid administration were recorded.

Results: The mean of the average oxygen saturation was significantly less in the control group in the 1st and 2nd day as compared to the laser group. The need for oxygen and the incidence of OSA in the first 3 days were significantly higher in the control group as compared to the laser group. The degree of edema showed no significant difference in the first day but was significantly higher in the control group in the 2nd and 3rd days. Hence, the need of steroids was significantly higher in the control group in the first 3 days.

Conclusions: Preliminary results showed that low level laser therapy is effective in reducing the incidence of early postoperative airway obstruction after SBF operations.

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* Corresponding author.
E-mail address: aemei.ibrahim@yahoo.co.uk (A.E. Ezzat).

http://dx.doi.org/10.1016/j.otorri.2016.01.006
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El uso de la terapia con láser de baja intensidad para reducir la obstrucción de la vía aérea postoperatoria temprana después del colgajo de Hogan modificado

Resumen

Introducción y objetivo: La más común de las complicaciones postoperatorias tras la cirugía de la insuficiencia velofaringea son el sangrado y la obstrucción postoperatoria de las vías respiratorias, o la apnea obstructiva del sueño. Por lo tanto, el objetivo de este estudio fue evaluar el efecto de la terapia láser de baja intensidad durante los primeros días del postoperatorio en niños sometidos a colgajo faringeo de base superior (SBF).

Métodos: Estudio clínico aleatorizado doble ciego en 30 niños, entre el grupo de láser y el grupo control, que fueron sometidos a SBF. El estudio se llevó a cabo en dos centros médicos académicos de atención terciaria, entre 2013 y 2015. Se registró grado de edema, la saturación de oxígeno, la aparición de apnea obstructiva del sueño y la necesidad de esteroides.

Resultados: Durante los 3 primeros días, la media de la saturación de oxígeno muestra cambios significativos entre los dos grupos. Por otra parte, la necesidad de oxígeno en los primeros 3 días muestra también cambios significativos entre los dos grupos. Así como la incidencia de apnea obstructiva del sueño. El grado de edema no muestra ningún cambio significativo en el primer día, pero sí en los 2 días siguientes. Por lo tanto, la necesidad de esteroides en los primeros 3 días también muestra cambios significativos entre los dos grupos.

Conclusiones: Los resultados preliminares mostraron que la terapia con láser de baja intensidad es eficaz en la reducción de la incidencia de obstrucción de vía aérea en el postoperatorio temprano después de las operaciones SBF.

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Introduction

Velopharyngeal insufficiency (VPI) occurs in about 20% of cleft palate (CP) patients after primary palatoplasty. The characteristic speech patterns of VPI are due to increased air transmission through the nasal cavity including; hypernasality, nasal emission, and weak pressure consonants and frications. Schoenborn described the inferiorly based pharyngeal flap procedure in 1876 for treatment of those cases. Later, San Venero-Roselli in 1935 designed the superiorly based flap (SBF). Multiple variations have been reported since. In 1973, Hogan used a myomucosal flap of the posterior pharyngeal wall. Later, Shprintzen (1979) modified this technique as ‘the tailor-made flap’, with the flap width determined by the degree of preoperative lateral pharyngeal wall adduction. The most common of postoperative complications are postoperative bleeding and airway obstruction or obstructive sleep apnea (OSA), postoperative airway obstruction incidence rates from 3% to 15%. Later, Liao et al. stated it is up to 32%. In fact, low-level laser therapy (LLLT) is a technological resource widely used in oral medicine and surgery with favorable results. Several mechanisms of biostimulation of human tissues and organs under LLLT are involved in reduction of edema as the anti-inflammation and re-establishment of arterial, venous and lymph microcirculation effect, consequently better tissue nutrition occurs. Although low-level laser has been applied in the medical filed for more than 25 years of practice, no studies were found in the literature involving incidence of postoperative edema and airway obstruction in patients undergoing SBF. Therefore, the aim of this study was to evaluate the effect of low-level laser therapy during the first postoperative days on children undergoing SBF in reduction of incidence of early postoperative OSA.

Material and methods

This study was a randomized double blind clinical study (the family and the assessing doctor were not informed about the group to which the child belonged during the medical assessment, except on the fourth postoperative day) done on 30 children undergoing secondary palatal operation between 2013 and 2015 (no lost or rejected cases). The study was conducted in academic tertiary care medical centers (Al-Azhar university hospitals and, Ain-shams University hospitals in Cairo-Egypt).

Our patients’ inclusion criteria were: 1 – Previous primary repair of the cleft palate (with or without a cleft lip or alveolus), 2 – non syndromic patients and 3 – patients with normal BMI (between the 5th percentile to ≤ the 85th percentile) according the US Centers for Disease Control and Prevention (CDC) growth charts. The Exclusion criteria included one or more of the following: 1 – the child being a part of syndrome, 2 – patients with obstructive sleep apnea syndrome, 3 – patient undergone previous surgery for VPI, 4 – patients with BMI ≥ the 85th percentile according the US-CDC growth charts, and 5 – mentally retarded patients.

The patients were randomly divided into two groups: 1 – laser group: included 15 patients who received LLLT with mean ± SD of age was 5.22 ± 2.53 and 2 – control group included 15 patients with mean ± SD of age was 6.42 ± 0.76. Regarding the patient epidemiology, there
Table 1  Descriptive statistics of type of operation, residency, age and gender distribution of patients.

<table>
<thead>
<tr>
<th>Items</th>
<th>Laser</th>
<th>Control</th>
<th>Total</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Area</td>
<td>Rural</td>
<td>7</td>
<td>46%</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Urban</td>
<td>8</td>
<td>54%</td>
<td>6</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>9</td>
<td>60%</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>6</td>
<td>40%</td>
<td>7</td>
</tr>
<tr>
<td>Age</td>
<td>Mean±SD</td>
<td>5.22±2.537</td>
<td>6.420±0.766</td>
<td>5.82±1.872</td>
</tr>
<tr>
<td>BMI</td>
<td>Mean±SD</td>
<td>39.13±21.10</td>
<td>41.56±21.73</td>
<td></td>
</tr>
</tbody>
</table>

Note: SD = standard deviation.
* Non significant (P ≥ 0.05).

was no statistically significant difference between the two groups regarding age values (P-value = 0.140), gender (P-value = 0.714), geographic distributions (P-value = 0.714), or BMI (P-value = 0.7498), this was described in details in Table 1.

The laser group received local application of therapeutic laser immediately after surgery. All the patients guardians signed a preoperative consent for the operation and for being a part of the research. All procedures performed in studies involving human participants were in accordance with the ethical standards of the National Research Centre-Egypt and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The work was approved by the ethical committee in National Research Centre-Egypt.

Laser technique

The participants were randomly assigned into a Laser and a control group. After suturing of the SBF, 15 patients had the operation site treated with Low-level Laser technique (LLLT) (SIR Laser Advance®, Sirona®-Germany). An interstitial technique of laser therapy was applied using a (970 ± 15 nm) diode laser type, using 220 μm² fiberoptic in continuous mode (CW), power was (P = 2 W) and the tissue dose was (35 J/cm²) according to Goulart et al. The treatment time (t) equation is; t = energy (J/cm²) × surface (cm²)/power (W). Intraoperatively, wet bandages were used on the oropharynx and wet compresses were used on the patient’s face to prevent burns secondary to the reflection of the laser beam. Both the surgeon and the anesthesiologist wore safety goggles during laser applications. A notice of laser-assisted surgery was posted on the door of the operating room to prevent inadvertent entry of persons without the standard safety gear during the procedure.

Operative procedures

All children underwent a modified Hogan’s flap "the tailor-made SBF” as described by Shprintzen. Splitting of oral mucosa of the palate was done for better exposure, the muscle layer splitting to allow muscle dissection and the nasal mucosa to allow tucking of SBF. The nasal mucosa of the palate was separated from the palatal muscles and oral mucosa. Additional two small horizontal incisions were done on nasal mucosa to facilitate accommodation of the SBF. The SBF was fashioned on the posterior pharyngeal wall and elevated off the bucco-pharyngeal fascia to a level above the soft palate. The pharyngeal donor site was closed by dissecting the lateral mucosal walls and suturing them together in mid line. Number 12 or 14 Nelaton catheters were placed through the nose and lateral portals to keep them open. The flap was tucked between the vertical incisions of the nasal mucosa of the palate and sutured there. Lining of the raw surface of the flap using nasal mucosa of the soft palate was done to reduce postoperative contraction.

Patient assessment

All children were monitored with continuous pulse oximetry for 72 h (3 days); both children in our series who experienced postoperative hypoxia were immediately identified and managed conservatively. If oxygen de-saturation occurs, the postoperative steroid therapy and the need of oxygen were recorded at the times of administration. In addition, the status of airway obstruction or obstructive sleep apnea (the apnea-hypopnea index is calculated as the average number of apnea and hypopnea per hour of sleep) was recorded on the patient’s sheets. Postoperative polysomnograms was required to those with saturation ≤92%, once it occur in those 3 days. In addition, the clinical assessment of was performed daily, for seven postoperative days then recorded on the patient sheets. The edema scale was designed by the authors as the following: grade 0: no edema, grade 1: local edema ≥1 cm² width of edema area, grade 2: 1–2 cm², grade 3: 2–4 cm², grade 4: ≥4 cm².

Statistical analysis

Non-parametric statistical analysis was done using Mann–Whitney test and parametric statistical analysis was done using Unpaired T test to compare between the Laser and control groups, the result was significant if the P ≤ 0.05. Through the professional statistics package SPSS® V20 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Comparison between the two groups was done after application of the LLLT to the patients. Over the first 3 days, the mean of the average oxygen saturation was significantly lower in the control group in the first day (t = 2.9300 & P-value = 0.0067) and the 2nd day (t = 2.2573 & P-value = 0.032)
while there was no difference in the 3rd day ($t = 1.9134$ & $P$-value = 0.066) between the control and laser group. Moreover, the need for oxygen in the 1st 3 days was significantly more in the control group than the laser group ($P$-value = 0.035).

The incidence of occurrence of OSA in the 1st 3 days was significantly higher in the control group as compared to the laser group ($P$-value = 0.035). The edema degree showed no significant difference between both groups on the first day ($-1.964$ & 0.050) while it was significantly higher in the control group in the second and 3rd days ($Z = -2.887$ & $P$-value = 0.004). Hence, the need for steroids in the 1st 3 days was significantly higher in the control group ($P$-value = 0.042). Those parameters were summarized in Tables 2–4.

Discussion

Significant velopharyngeal insufficiencies (VPI) usually require surgical management of the palate. Surgical techniques for correction of VPI include SBF, posterior pharyngeal wall augmentation, palate re-repair, and velar muscle reconstruction. Recent studies discussing SBF complications report wide array of possible occurrences. Postoperative respiratory obstruction and OSA are serious complications of those operations which may lead to death. SBF may obstruct upper airway severely; hence these children will require urgent interventions such as flap take-down, continuous positive airway pressure, or a tracheotomy.14-17 In which we did not need to do in any of our patients.

In children, apnea–hypopnea index greater than 1 or minimum oxygen saturation of less than 92% is considered abnormal. In the case of an apnea hypopnea index (AHI) of 5–10 (mild to moderate OSA) or more than 10 in a child who is 12 or younger, this indicates moderate to severe pediatric OSA.13 Edema is the main cause of postoperative airway obstruction and OSA in such patients, which usually depends on the duration of surgery, traumatization of the soft tissues and the individual response to edema formation. Other causes could be blood clots or inappropriate size of flap

| Table 2 Analytic statistics and results of unpaired $T$ test for comparison of postoperative oxygen saturation between the two groups. |
|---|---|---|---|
| **The mean of the average oxy. saturation** | Laser | Control | **Unpaired $T$ test** |
| **Mean ± SD** | **Mean ± SD** | **$T$** | **$P$-value** |
| 1st day | 95.266 ± 2.914 | 90.800 ± 5.709 | $t = 2.9300$ | 0.0067† |
| 2nd day | 94.272 ± 1.762 | 91.432 ± 4.543 | $t = 2.2573$ | 0.0320† |
| 3rd day | 96.783 ± 1.433 | 94.854 ± 3.632 | $t = 1.9134$ | 0.0660‡ |

Note: $SD = $ standard deviation.
† Non significant ($P \geq 0.05$).
‡ Significant ($P < 0.05$).

| Table 3 Analytic statistics and results for comparison of The need for oxygen, the need for steroid and the Early OSA in the two groups. |
|---|---|---|---|
| **Items** | Laser | Control | **$P$-value** |
| **$N$** | **%** | **$N$** | **%** | |
| The need for Oxygen in the 1st 3 days | 1 | 6% | 7 | 46% | 0.035† |
| The need for Steroid in the 1st 3 days | 0 | 0% | 5 | 33% | 0.042† |
| Occurrence of OSA in the 1st 3 days | 1 | 6% | 7 | 46% | 0.035† |

Note: † Significant ($P < 0.05$).

| Table 4 Analytic statistics and results of Mann–Whitney tests for comparison of edema degree in the two groups. |
|---|---|---|---|
| **Edema degree** | Laser | Control | **Mann–Whitney test** |
| **Mean ± SD** | **Mean ± SD** | **$Z$** | **$P$-value** |
| 1st day | 3.400 ± 0.548 | 4.000 ± 0.000 | $-1.964$ | 0.050† |
| 2nd day | 2.200 ± 0.447 | 4.000 ± 0.000 | $-2.887$ | 0.004† |
| 3rd day | 2.200 ± 0.447 | 4.000 ± 0.000 | $-2.887$ | 0.004† |

Note: $SD = $ standard deviation.
† Non significant ($P \geq 0.05$).
‡ Significant ($P < 0.05$).
which is rare. Sirois et al. noted that early postoperative polysomnograms were positive for obstructive apnea in 35% of patients. Follow-up polysomnograms during the following months indicated that none of the tested children showed evidence of obstructive apnea. This correlates with our finding, where early postoperative OSA occurred in 46% of the control group, and in 6% of the laser group with significance difference between both groups.

Snoring is expected after SBF in the postoperative period. However, postoperative obstructive airway will need treatment. Steroids can be used to decrease surgical edema, but should not be used on routine basis because of their detrimental effects on wound healing. Occasionally, continuous positive airway pressure may be used to improve obstructive events until the postoperative situation subsides. In our study we found that the need for oxygen was in 46% of patients and the need for steroid was in 33% of patients in the control group. However, the need for oxygen was in 6% of patients and there was no need for steroid treatment in the laser group patients; with significant difference between both groups.

We have used diode lasers which use semiconductor [Gal-
lum aluminum arsenide (GaAs) and helium–neon (He–Ne)] as the source for emission. Diode lasers wave length used in oral cavity vary between approximately 800 nm and 980 nm. Hence, we used wave length 970 ± 15 nm. The Food and Drug Administration (FDA) has classified the most commonly used low-level laser therapy (LLLT) as class III, no-significant-risk. We believed that the LLLT is effective as anti-edematous tool and reduced the postoperative edema which is the main cause of the postoperative respiratory distress in cases of SBF. However the exact mechanism is not yet known, several experimental studies showed LLLT to have a beneficial effect on cell and tissues. These remarkable effects were reported for treatment of a broad range of conditions such as musculoskeletal disorders, wound healing problem, and scarring. The anti-edematous effect of LLLT could be primarily due to the inhibitory effect of laser irradiation on the increase in vascular permeability during the occurrence of an acute inflammation. Furthermore it is believed that laser irradiation induces an increase in number and diameter of lymph vessels while simultaneously decreases the vessel permeability. In addition, Laser therapy stimulates cell growth and division of cells such as leukocytes and phago-
cytes and improves blood circulation in the irradiated tissue and facilitates the healing process, this decreases edema. For the previous possible mechanism as an anti-edematous and the low risk of LLLT, we decided to use the LLLT in our study. We found that the edema degree significantly decreased in the 2nd and 3rd day in the laser group. Hence, we found out that LLLT is effective as anti-edematous factor. Hence, the value of the usage of LLLT in patient with VPI undergoing SBF is very useful.

Limitations

Despite there are a good result of our report, the small size of the sample cannot allow us to give full orientation of outcomes. Hence, we encourage more patients to undergo the new technique and a longer time for follow-up.

Conclusion

Preliminary results showed that low-level laser therapy is effective in the reduction of the incidence of early OSA after SBF operations due to its anti-edematous effect.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Conflict of interest

The authors declare no conflict of interest.

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