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"CAROL DAVILA", BUCHAREST

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MEDICINE

STUDY ON THE MULTIMODAL, MULTILEVEL AND STAGE APPROACH TO OBSTRUCTIVE SLEEP APNEA SYNDROME

PHD THESIS SUMMARY

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I. GENERAL PART

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1. History of sleep related breathing disorders

The pathology of sleep was a point of interest in the studies of the great university centers in the 20th century, a great progress was achieved in 1953 when the REM phase of sleep (rapid eye movement) was discovered and correlated with the appearance of dreams, by Professor Nathaniel Kleitman and his student Eugene Aserinsky [3]. It was only in 1965, when the first sleep study was carried out, that the first episodes of apnea were recorded. In 1970, William Dement founded the first sleep study clinic in America at Stanford University. Between 1975 and 1980, 319 articles on sleep pathology were published, and in 1978, JE Remmers et al demonstrated that the main location of obstruction during an apneic episode is the oropharynx and not the larynx [4]. Since the 1980s, polysomnography (PSG) has become the gold standard in the diagnosis of sleep disorders [3].

2. Modern definition of sleep related breathing disorders

2.1. Definition. Classifications.

Respiratory pathology during sleep is a common disease among the general population, with an incidence of approximately 20%, which translates into a major public health problem [5].

According to the International Classification of Sleep Disorders, 3rd Edition, from 2014 and other international reference guidelines, breathing pathology during sleep is divided into several broad categories [6-8]:

1. Simple symptoms (habitual snoring)

2. Sleep hypoventilation syndromes

3. Central Apnea Syndrome (CAS)

4. Complex Sleep Apnea Syndrome (CompSAS)

5. Mixed sleep apnea syndrome (SAM)

6. Obstructive sleep apnea syndrome (OSA).

2.2. Obstructive sleep apnea syndrome

Obstructive sleep apnea syndrome (OSA) is defined as a repetitive, partial or complete collapse of the upper airway during sleep leading to episodes of hypoxia and sleep disruption [9]. It is the most common sleep disorder and a cause of concern worldwide, both among the general population and among aviation personnel.

A. Upper airway resistance syndrome (UARS) is a relatively recent entity, but not unanimously accepted. The International Classification of Sleep Disorders, Third Edition, of 2014 recommends incorporating UARS into OSA due to the pathophysiological similarity between the two [10]. However, many clinicians define cases in which we encounter symptoms of OSA (snoring, daytime sleepiness and decreased airflow), with polysomnographic criteria of sleep fragmentation but minimal episodes of apnea or hypopnea (Respiratory Disturbance Index <5) and without changes of oxyhemoglobin values as UARS and separates it from OSA [11].

B. Obstructive sleep apnea syndrome consists of respiratory episodes of hypopnea, apnea, and cortical microarousals.

• **Obstructive hypopnea** is the decrease in respiratory flow:

Greater than 50% of the pre-event basal amplitude for more than 10 seconds OR a perceptible reduction in airflow associated with either an oxygen desaturation greater than 3% compared to the pre-event basal value or a microwake (Chicago criteria) [12].

With at least 30% of pre-event basal amplitude for at least 10 seconds using nasal pressure, PAP device flow or an alternative hypopnea sensor, and an oxygen desaturation of at least 4% from pre-event (CMS Criteria- Centers for Medicare and Medicaid services) [13].

• **Cortical microawakenings (RERA)** are defined as respiratory sequences of at least 10 seconds characterized by an increase in respiratory effort or by a flattening of the portion

the inspirators of the respiratory curve leading to a microwake and when these respiratory events do not meet the criteria of a hypopnea or apnea episode [13].

• **Obstructive apnea** is a decrease of at least 90% of the maximum peak amplitude compared to the maximum basal amplitude before the event for at least 10 seconds as measured by an oronasal thermal sensor, PAP device or other alternative apnea sensor, associated with continuous inspiratory effort or increased throughout the duration of the respiratory pause [13]. The presence of inspiratory effort differentiates obstructive apnea from central apnea, where inspiratory effort is absent [13].

3. Etiology of upper airway obstruction

The upper airway (CRS) begins with the nasal vestibule and ends with the larynx. OSA can be due to either a static obstruction, a dynamic obstruction, or a combination of these. The main causes of nasal obstruction are: deviation of the nasal septum, oversized nasal turbinates (by hypertrophy or by hyperpneumatization - concha bullosa), nasal valve insufficiency, choanal atresia - rarely found in adults, malignant or benign neoplastic processes.

Deviation of the nasal septum is one of the most common causes of nasal obstruction. A nasal septum located perfectly on the midline is very rare, therefore a certain degree of deviation is unanimously accepted, when it does not cause obstruction [14]. Another cause of nasal obstruction reported in the specialized literature is chronic hypertrophic rhinitis. Benign tumor pathology of the nasal cavity most often consists of simple nasal polyps, sinus-choanal polyps, inverted papilloma. The most common malignant tumors of the nose are squamous cell carcinomas [15]. Obstruction at this level has the effect of a breathing bypass, with patients having to breathe through the mouth, which produces changes in the quality of the breathed air as well as the oro- and hypopharyngeal structures.

Another cause of nasal obstruction, but originating outside the nasal cavity, is caused by space-replacing processes at the level of the first pharyngeal floor, the nasopharynx. Most often, the hypertrophy of the lymphatic tissue of the pharyngeal and tubal tonsils blocks the choanal openings making it impossible for the air flow to the oropharynx and making oral breathing necessary.

The oropharynx, the middle portion of the pharynx, is bounded between the posterior region of the hard palate and the base of the epiglottis. It also plays an important role in the causes of CRS obstruction, fundamental in the pathophysiology of sleep apnea syndrome, and is in turn divided into two floors: retropalatal and retroglossal [16]. The lateral and posterior retropalatal oropharyngeal walls have in their composition the pharyngeal constrictor muscles (superior, middle and inferior) alongside islands of adipose tissue whose sizes vary directly proportional to the body mass index (BMI) of the subject [17-18]. The soft palate together with the lute can present dimensional peculiarities that can cause obstruction. With advancing age, the tissues lose their tonicity, this phenomenon also affecting the soft palate, it becoming plunging, and the lute is sucked in during inspiration, favoring its elongation even more. In the thickness of the oropharyngeal walls in the retroglossal region, in addition to the pharyngeal constrictor muscles, we find the hyoglossus, styloglossus, stylohyoid, stylopharyngeus, palatoglossus and palatopharyngeal muscles [17-19]. Hypertrophy of the palatine tonsils can cause obstruction especially when they are "kissing tonsils" leading to the considerable reduction of the oropharyngeal isthmus and plunging posteriorly in the supine position, narrowing the pharyngeal respiratory lumen. At the base of the tongue, we find the lingual tonsil, which can be constitutionally enlarged, especially in the case of overweight patients or secondary to gastroesophageal reflux disease. Tumor masses that can narrow the respiratory lumen can also be present at this level, most often in the case of patients who drink and smoke. The epiglottis, through variations in shape and position, can play an important role in sleep apnea syndrome. In the case of a healthy patient, the epiglottis, during swallowing is positioned over the aryepiglottic folds, covering the glottis. In patients with laryngomalacia, the epiglottis reaches this position during inspiration.

Laryngomalacia, a condition found mainly in newborns and children, can also be found in the adult population, in a much smaller number. Laryngomalacia occurs in the following cases:

- Very short aryepiglottic folds leading to the internal curvature of the epiglottis and the blocking of the respiratory space during inspiration.

- The epiglottis is abnormally long and flaccid, favoring diving by covering the glottic space in inspiration.

- Oversized arytenoids obstructing the respiratory tract by anterior diving in inspiration

- The epiglottis, which physiologically is positioned superiorly in inspiration, ends up being angled posteriorly, acting as a closed valve in inspiration [20-22].

Although many of the structural changes or space-replacing processes at the level of the larynx are less often incriminated in OSA, most of them rather cause insufficient breathing due to obstructive causes and therefore should not be overlooked.

The hypopharynx, the lower floor of the pharynx extends from the level of the pharyngoepiglottic folds caudal to the level of the lower edge of the cricoid cartilage, from where it continues with the cervical esophagus [16-17]. The most common obstructive causes at this level are space-replacing masses or developmental anomalies.

OSA has a higher prevalence in the adult male population than in females, but increases in both sexes with age. An explanation for this may be the length of the respiratory tract, which according to measurements published by several authors, is greater in men than in women [23-25].

Apart from the soft tissues that make up the upper airways, the adjacent bony structures play an extremely important role in the size of the airway and in the occurrence of sleep apnea syndrome [26]. Cephalometry provides important information about bone abnormalities in patients with sleep apnea syndrome. Many of the published studies document the measurements of the craniofacial architecture in orthostatism and provide information in two dimensions with low utility in the evaluation of the upper airways because in the supine position the ratios change considerably [27]. The oral cavity along with the dentition also plays an important role in sleep apnea syndrome.

Assessment of the oral cavity and dentition is of particular importance in determining the cause of sleep apnea syndrome. Occlusion evaluation should be performed to determine the presence or absence of posterior transverse discrepancies whether due to skeletal, dental, functional or a combination thereof. It is necessary to note the dimensions and shape of the palatal vault as well as the dental arches. The skeletal changes of the jaw with a role in sleep apnea syndrome can be defined as:

- A narrow and high palatal vault;
- Pointed vault;
- Unilateral or bilateral inclination of the alveolo-maxillary arches causing malocclusion.

Also, cephalometric measurements can be corroborated with anthropometric ones in obtaining a predictive index of the severity of the sleep apnea syndrome [28-30]. Dynamic changes also play an important role in the etiology of OSA. Chiu et al [31] published a study that concludes that in the supine position there is a redistribution of the extracellular fluid and this fact can lead to the narrowing of the pharyngeal respiratory lumen. Another study reports a causal link between the presence of leg edema (in patients without cardiopulmonary pathology) and the decrease in pharyngeal diameter [32], with them having a higher hypopnea apnea index.

4. Symptomatology

The patient with suspicion of OSA will present to the sleep doctor complaining of nocturnal and/or diurnal symptoms. Nocturnal symptoms are generally noticed by the family and less often by the patient:

- The snoring
- Episodes of apnea
- Sensation of suffocation/drowning
- Arousals/Restless sleep
- Bruxism - Nocturia
- Insomnia - BRGE
- Dry mouth sensation

Diurnal symptoms are generally those that the patient feels the most and that affect their daily life:

- Excessive daytime sleepiness and fatigue
- Morning headache
- Memory and concentration disorders
- Decrease in work capacity
- Depression and anxiety
- Irritability
- Erectile dysfunction

5. Risk factors

The main risk factors incriminated in the occurrence of breathing disorders during sleep such as obstructive sleep apnea syndrome are:

- Increased BMI. More than half of OSA patients have a higher-than-normal body weight, being either overweight or obese. With each unit increase in BMI, the risk of developing OSA increases by 14%, and a 10% increase in weight increases the risk of developing moderate or severe OSA by 7 times [33]. However, after the age of 60, the importance of BMI decreases, with other factors likely to intervene.

- Increased neck circumference also plays an important role in OSA. A value greater than 43cm in men and 38cm in women significantly increases the risk of developing this pathology [33].

- **Male sex**. Although the reasons why the prevalence of OSA is higher in the adult male population are still unclear, it is believed that the length of the upper respiratory tract, the specific mode of distribution of fat, neurochemical control mechanisms and sex hormones make the difference [34].

- **The upper airways** are narrowed either conformationally or through pathological changes in their structure. Chronic nasal obstruction, hypertrophy of Waldeyer's lymphatic triangle or tumoral pathology at the naso-pharyngo-laryngeal level may represent risk factors for the development of OSA.

-**Old age.** The prevalence of OSA among middle-aged adults ranges from 4% to 9%. In the case of those over 65 years of age, the prevalence reaches 10% either due to the decrease in the tonicity of the soft tissues (decrease in the level of collagen) in the upper airways or due to the decrease in the central capacity to maintain their tonicity [35].

- Family history of OSA. The idea of genetic transmissibility of familial predisposition to develop OSA was first documented by Strohl in the 1970s [36]. Between 25% and 40% of patients with OSA have a family history of this respiratory disorder, which indicates the possibility of inheriting the anatomical abnormalities that lead to its appearance [34].

- Ethnicity. OSA has a higher prevalence in the African American and Hispanic population than in the Caucasian population [37–39].

- Consumption of alcohol or sedatives produces additional relaxation of the soft tissues at the level of the upper airway increasing the chances of collapse and obstruction at this level.

- Smoking is considered a risk factor for OSA through chronic inflammation and changes in the mechanical and neural properties of the CAS leading to a much easier collapse [40].

- **Hypothyroidism**

- **Pregnancy** is also associated with the appearance of breathing disorders during sleep, especially in the third trimester due to weight gain. A small percentage of pregnant women end up developing OSA, most of whom only have habitual snoring. This is due to some physiological changes during pregnancy that have a protective factor against OSA: hyperprogesteroneism and reduced duration of sleep in the supine position.

6. ENT clinical examination in the patient with OSA

The management of OSA was for a very long time the prerogative of the pulmonologist, but recently, due to the complexity of this pathology, several specialties have been involved in both diagnosis and treatment, as is the case of otorhinolaryngology. The role of the ENT doctor has been underestimated, although he is the only one who can make the topographical diagnosis of upper airway obstruction and also surgically intervene in their resolution. The ENT consultation in the case of a patient with breathing disorders during sleep should include a clinical examination, a fiberoptic examination and the recommendation for performing complementary paraclinical examinations.

Fiberoptic examination in the case of patients with OSA is indicated to be performed in the sitting and supine position, classically and with revealing maneuvers of dynamic obstruction such as the Muller maneuver and the snoring simulation maneuver both retropalatal and retroglossal.

The Muller maneuver (MM) is the attempt to inhale air with the mouth closed and the nostrils pinched, which in some cases leads to the collapse of the upper airway.

The simulated snoring maneuver (MSS) is performed with the mouth open simulating a noisy inhalation. At this point, the type of narrowing of the respiratory lumen should be assessed: by the proximity of the anterior wall to the posterior wall, by the proximity of the lateral walls, or by the proximity of all walls such as the mouth of a bag.

7. **Establishing the diagnosis in the patient with OSA**

A definite diagnosis of sleep apnea syndrome is established by a sleep study. The gold standard worldwide is polysomnography. Because of the high cost and the limited spread of centers that can perform this complex assessment, diagnosis is often made using a nocturnal ventilatory polygraph. The device used for this investigation is easy to use by the patient and does not require hospitalization.

According to the international classifications, depending on the number of episodes of apnea and hypopnea per hour, both the diagnosis and the degree of severity are established:

- Sleep within normal limits with AHI below 5 episodes/hour.

- Obstructive sleep apnea syndrome with AHI between 5 and 15 episodes/hour

- Moderate obstructive sleep apnea syndrome with AHI between 15 and 30 episodes/hour

- Severe obstructive sleep apnea syndrome with AHI over 30 episodes/hour.

Apart from the hypopnea apnea index, other parameters to consider are the respiratory disturbance index, RDI, desaturation index, ODI, number of RERA episodes, number of central cause apneas and body position. Apnea episodes should also be corroborated with body position, most of the patients having these respiratory events in the supine position.

8. Drug induced sleep endoscopy (DISE)

Although the gold standard in the treatment of OSA remains the use of PAP devices, there are a multitude of patients who are noncompliant for financial, psychological, or machine intolerance reasons. Because episodes of apnea and hypopnea occur predominantly during sleep, it is necessary to assess the upper airway while the patient is asleep. In order to determine with certainty, the location of the obstruction and to be able to make the correct surgical indication, many patients must be evaluated endoscopically during sleep.

DISE is a rather resource-consuming investigation, as it requires, in addition to high-performance ENT specific equipment (flexible endoscope with the possibility of recording, attached microphone), a device for monitoring the depth of sleep and one for monitoring vital functions (BP, pulse, saturation in O2) as well as the presence of an anesthesiologist to adjust the doses of sedative substances, administer them and be prepared to intervene in case of deterioration of vital functions.

Most often, substances such as propofol and midazolam are used to induce sleep, but the best relaxation is obtained using propofol. It is recommended to be administered using TCI (target control infusion), and sleep depth monitoring can be done using BIS (Bispectral Index) or the Entropy Module [41]. Drug doses are continuously adjusted according to patient response, ranging from 2 to 4 mcg/ml titrated.

Noting obstructive changes in the upper airway is very important. Unfortunately, until now, there is no unanimously accepted system, but the most commonly used is the NOHL system (Nose, Oropharynx, Hypopharynx and Larynx) for defining the degree of obstruction.

Although the use of sedation in the evaluation of upper airway collapsibility can give false positive results, it remains a useful complementary method to awake fiberoptic examination, which can provide valuable information that can change the perspective of case management

9. Conservative treatment of OSA

9.1. Hygienic-dietetic regimen

The main hygienic-dietary recommendations to reduce the risk of apnea-hypopnea episodes are to avoid substances that cause additional relaxation or chronic inflammation of the mucosa of the upper respiratory tract, but also to avoid rich meals before going to bed. Consumption of alcohol or sleeping pills can promote pauses in breathing during sleep. Smoking, in addition to the unwanted cardiopulmonary effects, produces a chronic inflammation of the pharyngeal mucosa favoring OSA. If the patient is a chronic alcohol user, it is indicated to refer him to a detoxification clinic because the chances of success without extrinsic support are minimal.

9.2. Postural therapy

The main risk factor and aggravating factor of sleep apnea syndrome is obesity. An increased body mass index is translated at the cervical level by excess adipose tissue at the parapharyngeal level that leads to the narrowing of the respiratory passage at the level of the upper airways. Also, the presence of an abdominal apron increases intrathoracic pressure increasing respiratory effort. During supine sleep, essential structures such as the soft palate, tongue base, and epiglottis can plunge posteriorly, producing upper airway obstruction and favoring OSA. The majority of polysomnographic studies with a body position sensor in patients with moderate or severe OSA have indicated a predominance of sleep in the supine position. The use of postural therapy has an important role in improving nocturnal symptoms [42-44]. To avoid sleeping in the supine position, several methods have been studied over time. There are several types of postural therapy devices commercially available. One of them, in the form of a belt that presents an important unevenness at the level of the thoracic spine, a fact that makes the supine position impossible. The cheapest, but still effective method is to make a pocket on the back of a t-shirt into which a tennis ball can be inserted. Another method available to the patient is to carry a backpack with tennis balls. There are also physiotherapists who can teach patients to sleep on their side.

9.3. Weight loss

Weight loss in patients with OSA is very important if they associate an increased BMI [45]. This process can have a major impact on disease severity, reducing excessive daytime sleepiness and increasing quality of life [46]. Weight loss is difficult and long-lasting and can be achieved through conservative methods (diet and exercise) or surgical (bariatric surgery). Regardless of the method chosen, once the target weight is reached, the patient must follow the principles of a healthy and balanced diet in order to maintain it.

9.4. Prosthetic therapy

Prosthetic therapy is a conservative method used in the treatment of OSA. In the case of patients with nasal obstructive syndrome due to internal valve insufficiency, a silicone prosthesis can be used to prevent the nostrils from collapsing during inspiration. They have the advantage of being easy to use and without the complications of surgery to restore the other nasal tripod.

Intraoral prosthetic devices represent a conservative option with very good results on the apnea-hypopnea index and better patient acceptability compared to CPAP devices [47]. These devices are generally indicated for patients with mild or moderate OSA but also for those with severe OSA who do not tolerate positive air pressure devices. There are 3 types of intraoral prosthetic devices:

- Mandibular advancement devices

- Tongue fixation devices (used in case of contraindication to the use of the first category)

- Soft palate lifting devices (no longer used in current practice)

9.5. Therapy with positive air pressure devices

Positive air pressure devices are the gold standard in the treatment of patients with OSA. The role of these devices is to prevent upper airway collapse, hypoxemia, and hypercapnia. For optimal results, these devices should be used for a minimum of 4 hours per night. However, in the case of patients with professions such as piloting, driving vehicles, it is important to use these devices for a longer period in order to be able to carry out their professional activity safely [48].

Depending on the type of pressure administered, they are divided into:

- CPAP devices with fixed continuous positive air pressure

- APAP devices with variable positive air pressure that automatically adjust

- BiPAP devices with positive pressure on two levels, inhale and exhale.

Alternatives to PAP devices:

- EPAP devices with positive expiratory pressure.

- Winx Sleep Therapy System oral negative pressure device.

All positive air pressure devices have three types of masks, nasal mask, oro-nasal mask and full-face mask. Choosing the right mask type is very important due to the major impact it has on patient adherence to this type of therapy. In most cases, the nasal or oronasal mask is associated with the highest rates of patient compliance.

10. Surgical treatment of OSA

Following the clinical and fiberoptic examination, the ENT doctor can indicate surgical intervention in the patient with OSA. These interventions are done after a prior use of PAP devices for at least 8-12 weeks, because the anesthetic risks in these patients are very high. Sometimes, in addition to the ENT consultation accompanied by the fiberoptic examination, an endoscopic examination in drug-induced sleep and radiological investigations may also be needed. After the objective establishment of the locations of the obstructions, the therapeutic surgical procedure is decided together with the patient, depending on his options. Separate operations on levels of obstruction are recommended in order to obtain the best results, taking into account the patient's quality of life in the postoperative period.

10.1. Surgery of the nasal cavity and nasopharynx

Restoring the patency of the nasal airway is very important for patients with OSA. The operating principles of these surgeries are the same as for any patient. Surgical interventions are performed under general anesthesia with oro-tracheal intubation under endoscopic or classical control. The following surgical interventions can be performed within the framework of nasal sinus permeabilization surgery:

- **Surgical interventions on the nasal valve:**
    - ♣ Nasal valve plasty (internal and/or external) using autologous grafts or silicone prostheses
    - ♣ Columella plasty
- **Surgical interventions on the inferior turbinates:**
    - ♣ Turbinate reduction with radio frequency
    - ♣ Turbinate reduction with coblation
    - ♣ Turbinate reduction with the shaver
    - ♣ Submucosal resection
    - ♣ Lateroluxation of the inferior nasal turbinates
    - ♣ Cryotherapy
- **Surgical interventions on the nasal septum:**
    - ♣ Septoplasty

- FESS (Functional Endoscopic Sinus Surgery).

Surgical interventions at the level of the nasal fossa are aimed at reducing OSA symptoms, increasing patient compliance when using PAP devices, especially those with a nasal mask and mandibular advancement devices [49].

The main surgical intervention for the nasopharynx is the ablation of hypertrophy of the lymphatic tissue at this level, called adenoidectomy. This operation is performed under general anesthesia, under transnasal endoscopic control or transoropharyngeal palpation.

10.2. Oral and hypopharyngeal surgery

Most obstructive causes of OSA are found at this level, and generally more than one surgical intervention is needed to resolve this area.

- Surgical interventions for retropalatal obstruction:

♣ Uvulovelopharyngoplasty
♣ The uvulopalatal flap
♣ Palatal implants
♣ Veloplasty RFITT.
♣ Lateral pharyngoplasty
♣ Tonsillectomy-

- **Surgical interventions on the retroglossal region**:

♣ Partial midline glossectomy
♣ Glossoplasty.
♣ Lingual tonsillectomy
♣ Radiofrequency volumetric reduction is another volumetric reduction technique of the retroglossal region

Surgical interventions of the epiglottis have the role of either volumetric reduction of the epiglottis or its repositioning.

- ♣ Epiglottoplasty
- ♣ Another way to remove the obstruction produced by the position of the epiglottis is to anchor it to the base of the tongue or to the hyoid bone [50].

- **Surgical procedures of the tongue** may also be considered in patients with retroglossal obstruction. Among them I remember:

- ♣ Genioglossal advancement procedure
- ♣ Hyoid bone anchoring
- ♣ Anchoring the base of the tongue with wires
- ♣ Mandibular advancement surgical procedure [51].

- **Any oro or hypopharyngeal tumor** mass that causes airway obstruction can be part of the etiology of sleep apnea syndrome and must be surgically removed.

10.3. Laryngeal surgery can provide objective results in the fight against OSA. At the level of the larynx, we can discuss the etiology of laryngeal stenosis, laryngomalacia or even malignant and benign tumor formations. If until 20 years ago many of these pathologies were addressed surgically with cold instruments and often through the open way, today, by increasing the spread of transoral laser surgery we can obtain benefits with very low mortality and morbidity [52].

10.4. Tracheostomy is a surgical intervention that is performed in very well selected cases and well established by good practice guidelines. This procedure has the role of creating a by-pass of the upper airways by bringing the tracheal lumen to the skin and most often in the cervical region. It is performed urgently, in the case of patients with acute respiratory failure due to obstructive cause of the oro/hypopharynx or the larynx, cold in the case of patients with prolonged orotracheal intubation, before the start of radiotherapy on the cervical region or in the laryngectomized patient [53]. In the case of OSA, this surgical intervention is limited to very well selected cases even if it leads to the almost complete disappearance of apnea episodes. In such cases, the tracheostomy is often a temporary one, which is maintained until at least partial resolution of the upper airway obstructions.

10.5. Stimulation of the hypoglossal nerve is a surgical procedure performed under general anesthesia through which a neurostimulator is implanted that acts selectively on the fibers responsible for tongue protrusion. This surgery is aimed at patients with moderate or severe forms who do not tolerate PAP devices. Studies have reported an important regression of symptoms [54-55].

II. **PERSONAL CONTRIBUTIONS**

11. Introduction

The multifactorial etiology and the plethora of clinical manifestations of OSA contributed to the relatively late (1970s) recognition and individualization of this condition. The effects of the inertia of insufficiently informed medical practice are felt even today, as there is still no universally accepted consensus on the definitions, clinical spectrum, pathophysiology, and treatment of obstructive sleep apnea. I believe that an important factor of the lack of a unified vision arises against the background of the involvement in the management of this syndrome of doctors from multiple specialties, both surgical (ENT, OMF, General Surgery) and medical (pneumology, cardiology, neurology). The present paper aims to unify the diagnosis and treatment plan in SOAS through a proprietary algorithm (abbreviated 3M) using a Multistep, Multimodal and Multilevel approach. This structured approach is supported by evidence-based medicine and can be used in both the diagnostic and therapeutic stages.

Since OSA has multiple pathophysiological mechanisms that are causally manifested in the form of equally varied clinical manifestations, we explored the possibility that the diagnosis should be carried out by going through several steps (Multistep) standardized according to the data in the literature. Each step involves the use of complementary diagnostic methods (Multimodal) being involved different diagnostic modalities from anthropometry to fibroscopy and from imaging to metabolic determinations. The third element of the 3M acronym refers to the seat or level (Multilevel) of the obstruction such as the nose, nasopharynx, oropharynx, hypopharynx and larynx or tissues covering the throat region. In simpler terms, several steps are taken (Multistep) in the diagnosis and assessment of the severity of the syndrome using varied methods (Multimodal) to establish the type and location of the obstruction (Multilevel) (Figure 11.1).

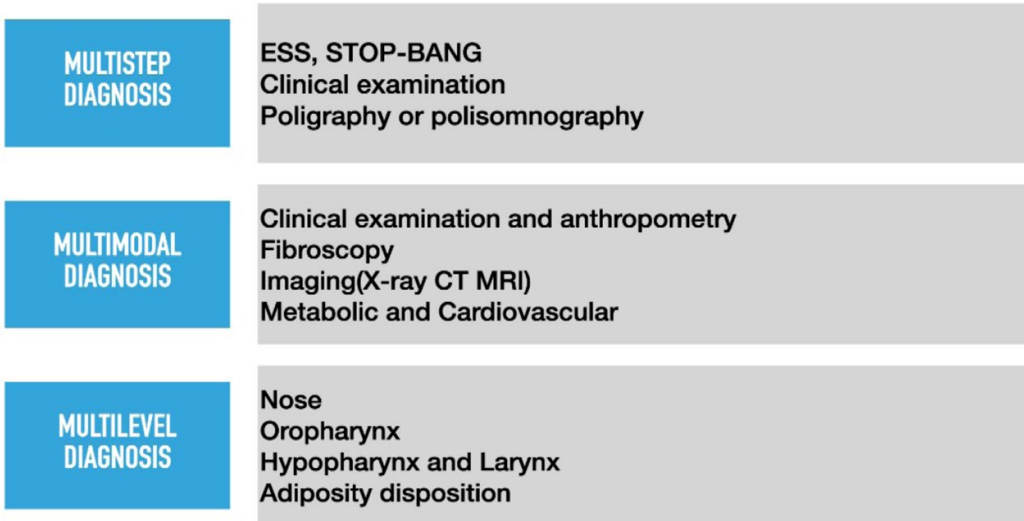


Image11.1. 3M diagnosis protocol

The diagnostic algorithm is duplicated by a treatment algorithm that respects the same principles: incremental steps are followed (Multistep), choosing different ways to solve the obstruction (Multimodal) depending on the level at which it manifests itself (Multilevel). So, we can divide the algorithm into a diagnostic and a therapeutic arm. The algorithm was designed precisely to ameliorate the great variability in the approach to SAOS and to reconcile the view of different specialties on its management (Image 11.2.).

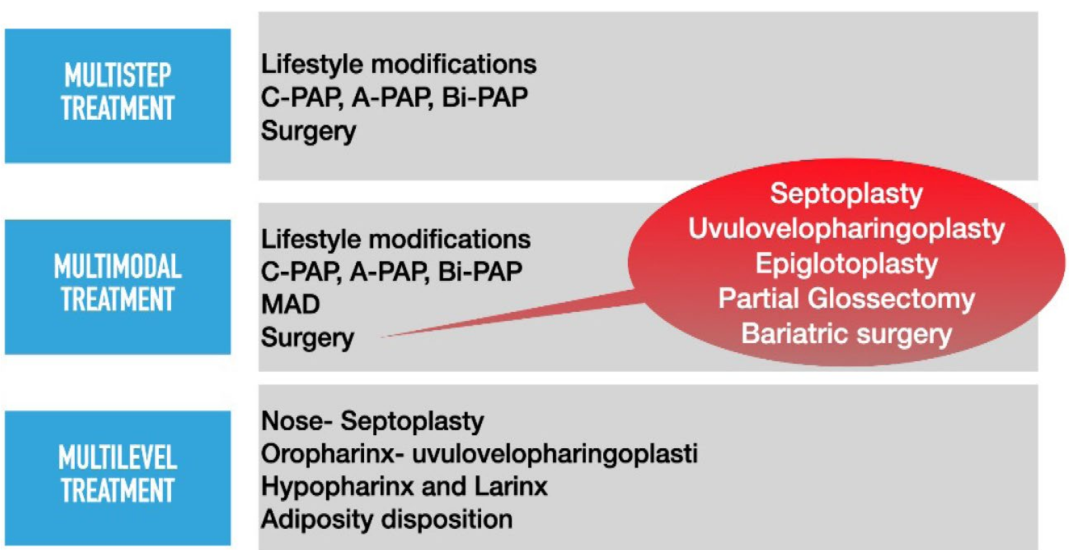


Image 11.2. 3M treatment protocol

In order to be able to predict which of the patients examined for symptoms suggestive of OSA require further investigation, it was necessary to use some screening tools. After studying the already existing questionnaires I decided to use the Epworth sleepiness scale and the STOP Bang questionnaire. The two screening tools use closed questions assigned a Likert scale subsequently operationalized numerically (Epwoth), or dichotomous responses (STOP Bang). After applying these questionnaires and directing the patients to perform a nocturnal respiratory polygraph, we looked for a correlation between the score obtained by the patients and the objective indices AHI, ODI and RDI by applying some statistical tests in order to establish the sensitivity and specificity of each of the two questionnaires in detecting the severity of OSA.

The weight status and other anthropometric measurements such as the circumference of the neck, the abdomen and the thyro-mental angle are closely related to the occurrence of obstructive sleep apnea syndrome, which is why we performed multiple statistical tests on the study group in order to establish their correlation with objective indices measured by ventilatory polygraphy nocturnal.

Apart from the fiberoptic examination in the awake state that provides information that often turns out to be distorted during sleep, OSA being a disorder that occurs eminently during sleep, we decided to use an additional investigation performed in drug-induced sleep to find the sites of occult obstruction and their correct addressing. Through DISE (medically induced sleep endoscopy), hidden dynamic changes of the upper respiratory tract can be observed during an awake endoscopy, whether with dynamic revealing maneuvers such as the Muller maneuver or the snoring simulation maneuver.

Once the diagnosis of OSA and its etiology is established by corroborating clinical and paraclinical data, legitimate questions arise regarding the sequence in which the causative factors can be removed or ameliorated and the manner in which this can be done. Thus, we performed an analysis of the patients to highlight the etiology of the obstruction and the frequency with which different sites contribute to the diagnosis of patients, as well as the rates of improvement of the subjective complaints and the objective parameters of OSA after the successive surgical removal of some sites of obstruction and the application of non-surgical conservative treatments surgical.

The lack of possibility of predicting the success rate of a surgical intervention on an obstructing site can represent a discouraging element for both the doctor and the patient. Unlike nasal obstruction where temporary removal of the septum or lower nasal turbinates is impossible due to lack of space and tissue mobility, or at the hypopharyngolaryngeal level where the structures are impossible to adjust temporarily due to their position, the oropharynx allows temporary modeling of the local anatomy. For this reason, we decided to perform a veloplasty simulation maneuver by anchoring the soft palate with two 8Fr Nelaton probes in preoperative drug-induced sleep endoscopy in order to establish the success rate of this surgical intervention.

Due to the multifactorial etiology of OSA and the large number of medical and surgical specialties involved in the management of this pathology, we considered it necessary to have a simple way to integrate all the medical information of a patient. One of the first measures we took in this direction of simplification and systematization was the introduction of a somnology file for each patient from the first contact with the team at our institute. This record is a generic term for all medical information related to the management of the patient with obstructive sleep disorders and contains all relevant data on the diagnosis, course and treatment of the disease. We found in the case of patients referred for apnea that there is no doctor to coordinate the diagnostic and therapeutic measures, which is why the condition is sometimes neglected and the treatment is instituted late. The somnology file proposes a common language between all members of the multidisciplinary team, a chronological ordering of investigations and a categorization of data and recommendations according to the 3M algorithm. I believe that this leads to an early diagnosis and the rapid establishment of therapeutic measures.

12. OSA's Multistep, Multimodal and Multilevel diagnostic algorithm

12.1. Study on the predictive value of subjective questionnaires in the severity of OSA

12.1.1. Introduction

Subjective questionnaires are used as a screening method in the detection of OSA because they are easy to apply and detect people with changes in sleep dynamics that can be attributed to obstructive sleep apnea syndrome. Intuitively, the more severe the organic dysfunction, the more important the physiopathological resonance should be. This assumption should translate into a direct correlation between the severity of OSA and that of clinical manifestations. Thus, the screening questionnaires could fulfill both the function of a detection tool because it highlights the existence of the syndrome, and that of a tool for measuring its severity because it tries to quantify its negative effects on the quality of life. The qualitative aspect of the questionnaire (screening) can be doubled by a quantitative one (severity measurement) if two essential conditions are met simultaneously:

I- the respondent interprets the questions pertinently and gives honest answers

II- questionnaires are correctly calibrated for screening and severity assessment.

The two questionnaires established in the study of sleep apnea, Epwoth and STOP-Bang, approach the screening of the syndrome by applying closed questions that were assigned a Likert scale later operationalized numerically (Epwoth), or dichotomous answers (STOP Bang).

12.1.2. Materials and methods

The study has a retrospective observational design applied to 77 patients who were treated for OSA in our Institute between 2014 and 2022; of these met the inclusion criteria 71.

We used Microsoft Excel to compile the database, SPSS version 20.0 and Epi info version 7 to perform descriptive and inferential statistical analysis, and Microsoft Word and Power Point to edit the document.

Both questionnaires were applied to the 71 eligible patients, the results being later analyzed together with the objective data from the nocturnal ventilatory polygraph.

12.1.3. Results and discussion

To analyze the correlation between the apnea-hypopnea index and the Epworth score, we used the Pearson correlation coefficient. According to this coefficient there is positive correlation between AHI and ESS and it is statistically significant. Thus, with a Pearson coefficient $r = 0.484$, with a significance threshold of 0.000, where $p < 0.001$, a positive correlation is demonstrated, which means that people with a high AHI level have a high ESS score and vice-versa versa. With an absolute value $r = 0.48$, we have an average strength of the link between the variables, since $r > 0.30$.

Starting from this reality, we can say that ESS has the potential to identify patients with sleep apnea syndrome, but in order to appreciate its effectiveness, it is necessary to calculate a threshold of sensitivity and specificity, to be able to characterize false negative and false positive results. These repercussions are important in the work because the objective the main objective of the thesis is to develop OSA diagnosis and treatment algorithms that match the current technical realities and improve the huge rates of underdiagnosis. We performed a calculation of the ROC curve (Receiver Operator Curve) in order to better understand the dynamics between the sensitivity and specificity of the ESS questionnaire. We reported the results to the AHI value which we found to correlate very well with the severity suggested by the subjective Epworth questionnaire.

The sensitivity of the test consists in its power to detect patients suffering from OSA, i.e. those patients called "true positive" and is a measure of the probability of the test to detect the condition. Although the value of the area under the curve leading to the rejection of the null hypothesis is 0.5, a good test must have a value above 0.6, and an excellent one above 0.9. The area value of 0.77 makes this tool very good suggesting a strong correlation between Epworth scores and OSA severity.

We applied an operationalization of the STOP Bang score to use cross-tabulation of AHI values by STOP Bang score. This operationalization consisted in classifying patients with medium and high scores in patients with a Sever score and patients with a low score in the Non Severe category. We observed that the median of these two subgroups is close but the T-test demonstrated a P-value of 0.14 indicating that the generalization that AHI can be predictive of high Stop Bang scores is not statistically significant.

12.1.4. conclusions

The ESS uses situations that the individual usually encounters, which gives it simplicity and accuracy in estimating the sleepiness scale, although it is eminently subjective. STOP Bang attempts to objectify measurements and provide standardization, greater reproducibility, but uses non-inclusive questions in the subjective section and scoring is laborious and error-prone. Moreover, in our study group there is no statistically significant correlation between the values of the STOP Bang questionnaire and the indices used to assess the severity of the apnea syndrome, which is why the specificity and sensitivity could not be calculated. STOP Bang, although it is a partially objective questionnaire, we believe that it loses in terms of accuracy in establishing the definition for subjective terms.

One of the explanations for this lack of statistical correlation between the severity of the syndrome and the results of the STOP Bang questionnaires may be given by the lack of obvious symptoms of OSA or their poor perception by the subjects. ESS, on the other hand, involving situational examples can detect apparently discrete manifestations and ignored by patients. Another explanation can be given by the current trend of increasing OSA incidence in the apparently risk-free population, women, patients aged up to 50 years or with close to normal anthropometry.

12.2. Clinical-anthropometric correlations in the development of a multimodal diagnostic strategy for OSA

12.2.1. Introduction

Obesity increases the incidence of OSA through several mechanisms: patients with an increased body mass index have a larger tongue volume, smaller caliber pharynx due to parapharyngeal adipocyte deposits, and reduced respiratory muscle strength. Also, due to obesity, there is also a decrease in total respiratory compliance by decreasing the compliance of both the chest wall and the lung compliance.

Anthropometric measurements are an essential tool in establishing the etiological diagnosis and the sites of obstruction because the establishment of some correlations between the patient's habitus and the level and severity of OSA leads to anticipatory assessments that facilitate the diagnosis (a patient with a visibly increased thyromentorial angle who does not state symptoms compatible with OSA would requires more thorough investigations because the chances of him suffering from a respiratory pathology during sleep are high).

12.2.2. Materials and methods

We designed a retrospective observational study for the 77 patients treated for OSA in our Institute between 2014 and 2022, 71 of them meeting the inclusion criteria:

The inclusion criteria consisted of:

- have symptoms suggestive of OSA

- have complete clinical documents

The exclusion criteria consisted of:

- incomplete medical documents

- patients with sleep apnea syndrome of central cause (non-obstructive)

We used Microsoft Excel to compile the database, SPSS version 20.0 and Epi info version 7 to perform descriptive and inferential statistical analysis, Microsoft Word and Power Point to edit the document.

For the 71 eligible patients, the values of the thyro-mention angle, abdominal and neck circumferences, as well as BMI were measured. Anthropometric determinations were analyzed in relation to the apnea-hypopnea index, an objective tool for quantifying the severity of OSA.

12.2.3. Results and discussions

The studied anthropometric indices (neck circumference, abdominal circumference and partly tiromentorial angle) are closely related to the body mass index (BMI). The study is based on the hypothesis that adiposity is an amorphous mass embedded in anatomical compartments divided by musculofascial structures and skin. Increasing or decreasing local adiposity should influence the airway. The fine line between overweight and obesity may be equivalent to the fine line between the patient with symptomatic OSA and the one with undiagnosed discrete clinical manifestations. As can be seen from the distribution of patients, only 11% of patients in this group have a normal BMI value. The vast majority are either overweight or obese which means that a decrease in body fat equates to a remodeling of the local anatomy and suggests that lifestyle changes would lead to improvement in OSA.

In order to investigate whether the AHI level is influenced by the thyro-mental angle, we grouped the patients in the group into 3 categories according to the value of the thyro-mental angle. The three categories include:

- Below normal category – patients with angle values below 130 degrees

- Normal category - patients with angle values of 130-150 degrees

- Above normal category patients with angle values greater than 150 degrees.

The 3 groups were compared simultaneously in relation to the AHI value (Below Normal-1, Normal-2, Above Normal-3), by applying One-way ANOVA.

Analysis of Variance results with an intergroup squared deviation of 1230.50 and an intragroup squared deviation of 9053.74, with an intergroup degree of freedom of 2 and an intragroup degree of freedom of 68. The F test $(2,68)=4.62$, with a Sig= 0.01, where $p<0.05$, which means that, as a whole, the Thyro-mention Angle influences the AHI value, these data representing the existence of global differences, without specifying which are the groups between which significant differences appear.

To investigate whether the age of the patients included in the group influences the AHI value, we divided the age of the patients into 4 groups (26-38 years -1, 39-48 years -2, 49-56 years -3, over 56 years -4) and -we compared simultaneously with the AHI level by applying the One-way ANOVA test. The results showed that there are no statistically significant differences between the groups, and the AHI level is not influenced by the age of the patients.

We also investigated the difference between the AHI level between women and men, we check if there is a significant difference between the two groups, by applying the t-test for two independent samples. To investigate the difference between the AHI level between women and men, we checked whether there was a significant difference between the two groups by applying the t-test for two independent samples.

In the comparative analysis it is observed that in the Levene test, Sig1=0.24, so $p> .001$, which means that we are facing the situation where there is equivalence between the two groups, the dispersion is similar and the equality of variances is accepted.

Thus, with a $t(69)=1.14$ and Sig 2=0.25, where $p> 0.05$, there are no statistically significant differences between the AHI level of male and female patients, which means that there are no significant differences between women and men regarding the AHI level. From this it follows that gender is not a predisposing factor for OSA in the studied group. From these results it follows that there is no anatomical variability between women and men in the neck.

To investigate the difference between the AHI level in patients who have normal neck circumference and the AHI level in patients who have neck circumference above normal, we checked whether there is a significant difference between the two groups by applying the t-test for two independent samples.

Thus, in the Levene test, with a t(69)=0.62 and Sig 2=0.004, where $p < 0.05$, there are statistically significant differences between the AHI level in patients with normal neck circumference and those with neck circumference above normal, which which means that there are significant differences between the two groups and the neck circumference influences the AHI level. These results support the initial assumption that the musculo-fatty envelope of the neck influences the respiratory corridor and the dynamic component of this complex is represented by adipose tissue, which is the only one that can be influenced. In other words, the increase or decrease of the cervical fat layer causes changes in the objective indices AHI, ODI and RDI.

To investigate the difference between the AHI level in patients who have normal abdominal circumference and the AHI level in patients who have abdominal circumference above normal, we checked whether there is a significant difference between the two groups by applying the t-test for two independent samples.

Of the total number of participants, 39 have normal abdominal circumference with a mean AHI level of 26.03 with a standard deviation of 7.31 and 32 have above normal abdominal circumference with a mean AHI level of 36.54 with a standard deviation of 14.26 , showing a mean difference in AHI level between the two groups.

Having a t(69)=-3.77 and Sig 2=0.000, where $p < 0.05$, there are statistically significant differences between the AHI level in patients who have normal abdominal circumference and those who have abdominal circumference above normal, which means that there are significant differences between the two groups and the circumference of the abdomen influences the AHI level. Abdominal adiposity as well as parapharyngeal adiposity influence the levels of objective indices in OSA, which means that the decrease in adiposity leads to an improvement in the severity of sleep apnea syndrome.

12.2.4. Conclusions

All anthropometric indices (BMI, neck circumference, thyro-mention angle and abdominal circumference) were statistically significantly correlated with the presence and severity of OSA. The circumference of the neck, the abdomen and the thyro-mental angle showed a stronger statistical correlation than the body mass index and this can be explained by the presence of adipocyte deposits predominantly at the parapharyngeal and abdominal levels.

13. The Multistep, Multimodal and Multilevel treatment algorithm of SAOS

13.1. Introduction

Although the gold standard treatment still consists of positive airway pressure devices, it does not provide a definitive treatment as functional surgery does, nor does it distinguish between apnea subtypes and their different pathophysiology. In addition, many patients have difficulty tolerating face masks, leading to low rates of treatment compliance and poor outcomes. In some cases, the use of these devices can lead to worsening of the syndrome if the patient presents with obstruction secondary to epiglottis collapse. The variety of obstructive sites and the multicausality of sleep apnea syndrome led me to seek multimodal therapeutic solutions targeting all obstructive sites in a multistep manner with the hope that my personal research will contribute to a paradigm shift in treatment in favor of airway surgery superior.

The treatment algorithm (Image 13.1.1) used for the patients included in this study involves going through several steps (Multistep), for the therapeutic addressing of all levels of obstruction (Multilevel) using different methods (Multimodal) in order to improve the health of the patients.

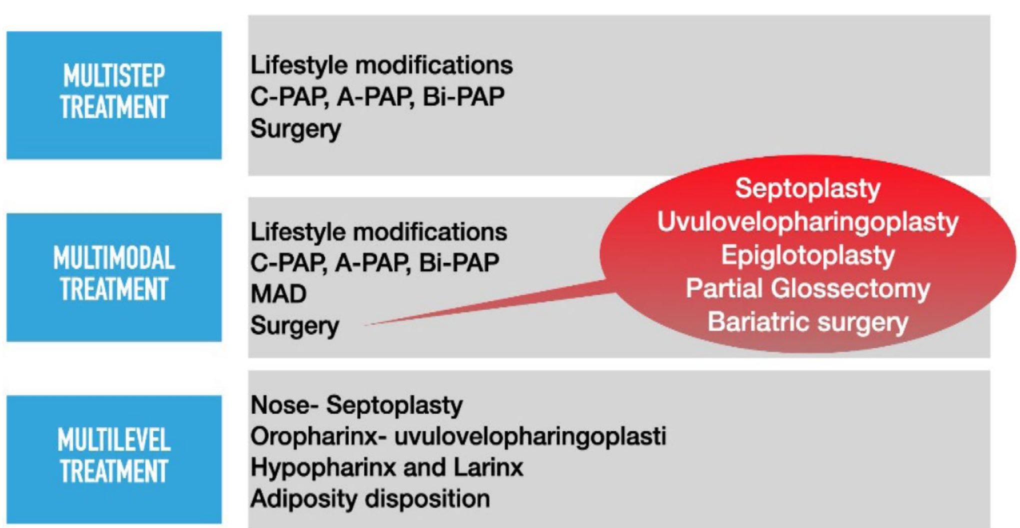


Image 13.1.1. 3M treatment protocol

13.2. Materials and methods

The study has a retrospective observational design applied to 77 patients who were treated for OSA in IFACF ORL and INMAS during 2014-2022. Of these, 71 met the inclusion criteria.

The inclusion criteria consisted of:

- to have a polygraphic diagnosis of OSA
- have at least one site of ENT obstruction with surgical indication
- to have complete clinical documents

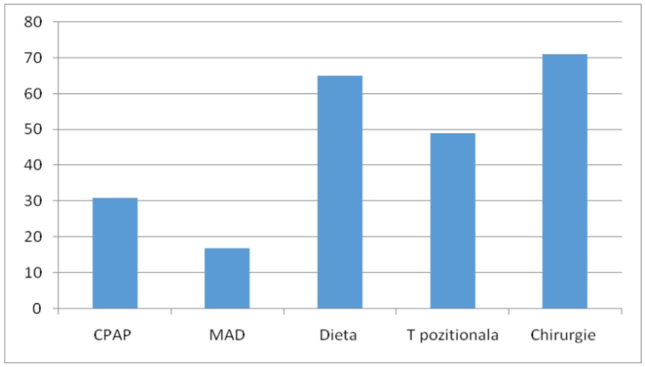
The exclusion criteria consisted of:

- incomplete medical documents
- patients with sleep apnea syndrome of central cause (non-obstructive)

13.3. Results and discussions

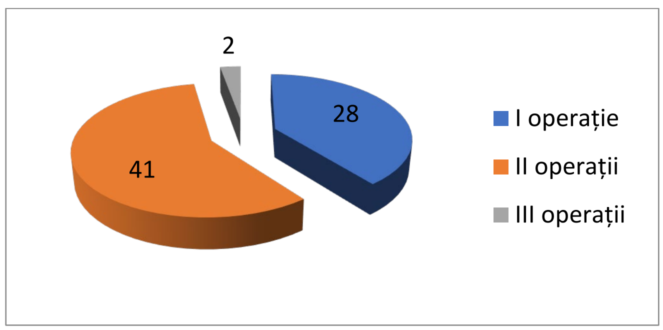
Obstruction, whether single or multiple, becomes clinically important by producing the symptoms that bring the patient to the doctor. The objective of these symptoms is done using the AHI, ODI and RDI indices which can be used implicitly and in the assessment of severity. So, the success rate of surgical interventions is assessed according to the changes in these parameters.

The multimodal, multilevel and staged treatment algorithm described previously was applied to the entire study group, depending on the needs of each individual patient (Graph 13.3.1.). Those with severe obstructive sleep apnea received preconditioning to lower cardiovascular risk with positive air pressure devices for approximately 3 months before surgery.



Graph 13.3.1. Graphic representation of the multimodal treatment indicated to patients in the study group.

All patients analyzed in this study required at least one surgical intervention. As can be seen from Graph 13.3.2., the majority had two surgeries at two different levels of obstruction. Only in the case of two patients it was necessary to perform 2 successive interventions.



Graph 13.3.2. Distribution of patients according to the number of surgeries performed per patient.

The surgical intervention to permeabilize the nasal passages consisting of septoplasty and/or lower mucotomy was the most frequently performed. The second most common operation was uvulopharyngoplasty, and at the opposite pole were suspended microlaryngoscopy and volumetric reduction of the base of the tongue (Graph 13.3.3.).

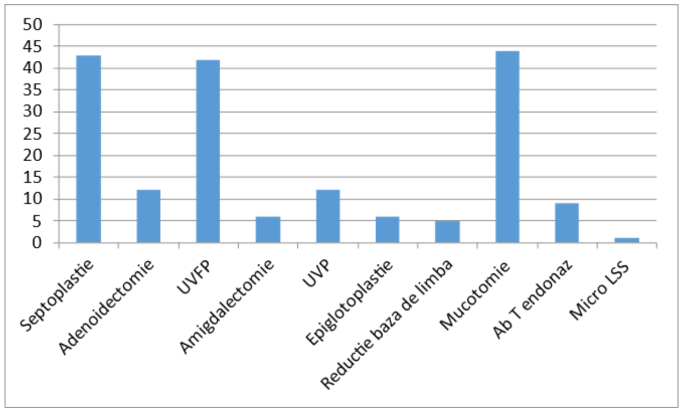


Chart 13.3.3. Distribution of patients according to the type of surgical intervention.

The effectiveness of the 3M treatment algorithm was verified at 3 months and 6 months after the initiation of therapy by comparing the objective indices AHI, ODI and RDI obtained from serial nocturnal respiratory polygraphs. To investigate the differences between the levels of these indices from the period before the initiation of therapy and the levels afterwards we used the t-test for paired samples. We obtained a statistically significant difference between the AHI, ODI and RDI levels at baseline and at 3 months and 6 months, so we can say that the multimodal treatment had an effect and improved the patients' condition.

In order to establish the subjective impact on the charges for which the patients presented themselves to the doctor, we analyzed the initial ESS scores compared to those obtained at 3 months and 6 months. In order to investigate these differences, we used the t-test for paired samples. Thus, a statistically significant difference is found between the initial, 3-month and final level of ESS, so we can say that the multimodal treatment had an effect and improved the condition of the patients. A progressive decrease in the scores of the ESS questionnaire is observed from one stage to another of the application of the 3M algorithm.

13.4. Conclusions

Due to the plurifactorial etiology of OSA, we cannot consider a single effective treatment for all patients. The 3M treatment algorithm discussed in this chapter is intended to demonstrate the need for targeted treatment for each patient based on the etiology and contributing factors of the obstruction.

Upper airway surgery aims to correct the location of the obstruction in order to restore an efficient airflow. Because many patients do not have single-level obstruction, surgeries are performed in stages to minimize postoperative complications.

Obstructive sleep apnea syndrome has a plurifactorial etiology, which is why the treatment must be targeted at the sites of obstruction, with patients undergoing the staged and individualized 3M algorithm in order to obtain optimal results.

14. Veloplasty simulation - clinical tool for preoperative validation of the benefit soft palate plasty in OSA with oropharyngeal location

14.1. Introduction

The understanding of the occurrence of obstruction in multiple sites in ENT obstructive pathology is closely related to the anatomical and functional peculiarities of the regions that provide air conditioning, phonation, the aero-digestive carrefour, the preparation of the food bowl and the regions that house the organs of the gustatory and olfactory senses. Detecting multiple sites involves avoiding the mirage created by identifying the first obstacle that often remains the only one for which a therapeutic sanction is proposed.

Precisely for this reason, I considered that the method proposed by Prof. Univ. Dr. Viorel Zainea, during the mentorship and coordination of this doctoral thesis, constitutes an innovative tool to establish the effectiveness of veloplasty in OSA with oropharyngeal headquarters. Few sites of obstruction lend themselves to simulating anatomical correction, and the oropharynx, by its tubular nature and the elasticity of its component structures, can be temporarily shaped by anchoring these structures to simulate the morphology that would result from surgery. This observation led to the proposal to temporarily anchor the soft palate with 8Fr Nelaton catheters placed transnasally and to perform dynamic measurements of the diameter of the oropharyngeal tunnel through which the airflow is admitted.

In more applied terms, the study below aims to demonstrate the hypothesis that temporary anchorage of the soft palate simulates the effects of veloplasty surgery. As the main objective, the confirmation of this hypothesis is equivalent to the confirmation of the veloplasty simulation method by which a short-term and minimally invasive procedure would save the patient from a surgical intervention that would bring him modest benefits.

14.2. Materials and methods

We proposed that patients who are apparently candidates for veloplasty undergo a preoperative procedure to simulate post-surgical conditions in order to establish the effectiveness of the intervention. The hypothesis of the veloplasty simulation method assumes that the temporary anchoring of the soft palate simulates the effects of veloplasty obtained through surgical intervention.

We considered eligible all patients with oropharyngeal location of the obstruction, regardless of the diagnostic stage in the 3M algorithm, but only 20 of them agreed to enroll in the study, because participation involved an additional perioperative procedure

All 20 patients in the study group presented obstruction at the oropharyngeal level. To assess the degree of dynamic obstruction or occult sites of obstruction, all patients underwent a perioperative DISE procedure. Following this assessment, an obstruction score was noted for the retropalatal and retroglossal regions. After noting the obstruction score, the transnasal soft palate was anchored using 8Fr Nelaton catheters.

After securing the soft palate in the desired position, the obstruction score was reassessed at the level of the same sites. If the anchoring maneuver caused an increase in the airway by at least 25%, the benefit of the maneuver is noted, which translates into an increased probability that the veloplasty intervention will produce the same effects. In other words, if the maneuver simulates a benefit, it is expected that after the intervention this benefit will manifest itself by improving the subjective and objective indices of obstruction.

Using computer programs such as SPPS, Microsoft Excel, PowerPoint and EPiInfo7, variables such as the Mallampati score and obstruction scores before and after anchoring the soft palate through the veloplasty simulation maneuver were analyzed.

14.3. Results and discussions

In the case of patients with retropalatal obstruction, the average of the obstruction score values, previously calculated by applying the anchoring maneuver, was 3.2, which corresponds to a high degree of airway obstruction. After performing the anchoring maneuver, the average obstruction score was 1.8, which is equivalent to a 43.75% decrease in the average, implicitly suggesting a decrease in the degree of obstruction. We performed the T-test on these results and the difference is statistically significant with a P below 0.001. Of all the patients enrolled in the study, 75% showed improvement in the retropalatal obstruction score after anchoring soft palate.

Patients who did not show a benefit as a result of applying the veloplasty simulation maneuver are patients in whom, although they had a retropalatal obstructive seat, the obstruction was caused by different structures in the oropharynx, such as the tonsils or the lateral walls of the pharynx, and could not benefit from soft palate surgery. We also observed that no patient showed relief of retroglossal obstruction by anchoring the soft palate, a result that was expected due to the local anatomy.

14.4. Conclusions

The ability to assess the potential benefit of surgery before it is performed provides vital information to the surgeon. Few anatomical structures in the human body allow such modeling. The tubular structure of the oropharynx, with predominantly muscular and mucous components, makes any operation at this level affect the suppleness, tonicity and dynamics of this anatomical segment.

The present study emphasizes the fact that 75% of the enrolled patients showed a benefit in terms of retropalatal obstruction from anchoring the soft palate with the 2 Nelaton probes, but comparatively, the study highlights the fact that performing this simulation maneuver does not involve the appearance of changes in the architecture retroglossal region.

15. The somnology file of the patient with OSA

15.1. Introduction

The management of chronic conditions involves a long-term relationship with the practitioner, an increased number of clinical visits, interdisciplinary consultations and generally a large volume of personal medical data. The fact that the diagnosis is multimodal would have a lower impact on compliance if the diagnosis was not addicted to multiple specialties. This is costly and time-consuming, leading to different interpretations and sometimes conflicting treatment recommendations. ENT doctors, neurologists, pulmonologists, dietitians, etc. unjustifiably dispute their exclusivity in various investment or treatment subfields of sleep apnea syndrome. This division of the guild, corroborated with often different perceptions on the management are the preamble of some diagnostic approaches that extend over periods of weeks or months.

These arguments led me to propose a tool with potential to improve the previously mentioned shortcomings. It has been intuitively called the somnological file, and it starts from the simple idea that the systematic approach reduces errors and improves results in all fields in which it has been applied, from engineering to the humanities.

The somnology file consists of a solution for dynamically compiling the patient's medical data and incorporating the diagnostic and treatment algorithms explained in this paper. Each patient who is included in the diagnostic algorithm will be opened a typed file containing a diagnostic section and a therapeutic section. To facilitate locating the data, the two sections have been color-coded and divided into an equal number of subcategories that represent mandatory steps that the practitioner should systematically follow with each patient.

15.2. Materials and methods

The working hypothesis that was the basis of the study was inspired by the empirical finding that the patients for whom we drew up a somnology file were seen more often for control and were much more compliant with the recommendations. Thus, we proposed to imagine a study that would test the following hypothesis: patients with a somnology record benefit from a faster and more effective management of OSA. The demonstration of this hypothesis, as the main objective of the study, would lead to the implementation of the somnology file in our current practice. Secondary, the study aims to analyze the degree of patient satisfaction, diagnosis and treatment times, treatment compliance and effective communication between medical staff and patients, these being the secondary objectives of the study.

To validate this working hypothesis, we imagined a retrospective observational study on an eligible group identical to the one enrolled in the main study with the help of which we studied the implementation of Multistep, Multimodal and Multilevel diagnostic and treatment algorithms. We established as the only eligibility criterion the requirement that the patients were enrolled in the 3M study, regardless of whether they had a somnology file or not, the exclusion criteria being: incomplete observation sheets, refusal to participate in the study, impossibility to contact the patient for the telephone questionnaire. Later, I used a questionnaire with 5 questions addressing the following as a study tool:

- the time elapsed from the presentation to the doctor until the diagnosis;
- the time elapsed from the diagnosis to the completion of the treatment;
- the general satisfaction of the patient in relation to his medical experience;
- the clarity with which the medical information was explained to him;
- how they value adherence to the doctor's recommendations;

The 5 questions of the study are accompanied by a numerical scale from 1 to 10 where 1 means very slow, very unclear, very dissatisfied, very non-adherent and 10 very fast, very clear, very satisfied, very adherent depending on the number of the question.

Of the 71 patients enrolled only 42 met the inclusion criteria mentioned above. Due to the fact that the patients were not managed by the same ENT team, the somnology file was not prepared for some of them. Even though this initially seemed a shortcoming, it was thus possible to divide the group into two distinct arms: with a somnology record and without a somnology record and to compare the experiences of the patients in the 2 subgroups between them.

Each question was assigned a score from 1 to 10 based on the patient's choice, and the data were then centralized in a Microsoft Excel worksheet. For descriptive statistics, Epi Info 7 contingent tables of the Means type were used, to which graphical representations of the Box and Whiskers type were applied. For inferential statistics, bivariate analysis of the items in the questionnaire was used to characterize the interdependence between them, measuring the Spearman correlation index. These correlations were then graphed. Editing was done in Microsoft Word and Power Point, SPSS and Epi Info 7.

15.3. Results and discussions

For the statistical analysis of the batch, we performed correlations between the values corresponding to the 5 items of the questionnaire using a Spearman bivariate analysis which is indicated in statistical operations with small batches.

There is a direct proportionality between all 5 items, which suggests that if the perception of the treatment time is good, then with a high probability the general satisfaction will be increased and the compliance will be higher. If the doctor managed to clearly and concisely explain the information to the patient, and he understood the disease and the diagnosis and management plan, then compliance and satisfaction will be higher. The analysis of the mode, i.e., of the most frequent value in the groups, shows that most patients reported a score of 7 if they did not have a somnology record and a score of 9 if they had a somnology record.

I would like to make a distinction between the speed with which a diagnosis is made and the perception of speed reported by the patient. This is where the doctor's ability to communicate, systematize and explain to the patient the diagnostic and therapeutic procedures as well as what a reasonable time to solve the case means. The questionnaire does not measure the diagnosis and treatment times but the perception of the speed with which they were implemented.

The overall satisfaction related to the entire medical process [Graph 15.3.1.] as well as the clarity of the explanations show superior results in the group with a somnological record. The important difference in favor of the somnological file is also maintained in the case of compliance.

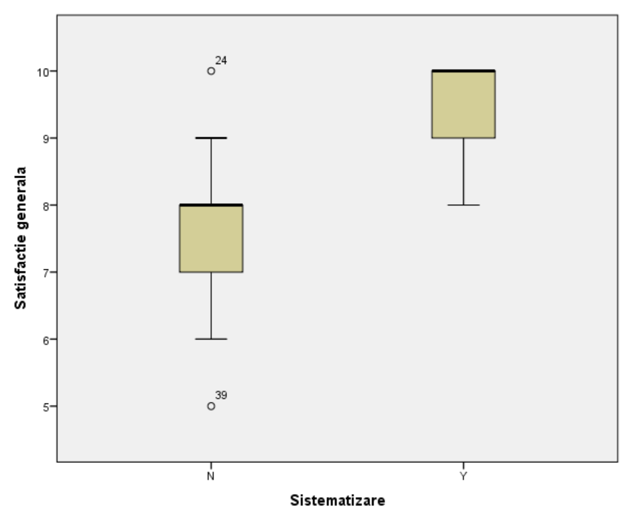


Chart 15.3.1. Graphical representation of descriptive statistics of overall satisfaction in relation to systematization.

15.4. Conclusions

Considering the data analyzed in this study, we can conclude that patients with a somnological file have a better perception of the diagnosis and treatment time, the clarity of the information received, compared to patients who do not have a somnological file. These aspects have the role of increasing treatment compliance, reducing the time until obtaining a final diagnosis, thus reducing waiting times, the economic burden on the health system and the need for exposure to the hospital environment, which is very important especially in a pandemic context. In order to extrapolate these conclusions to the general population, a larger study with a significantly larger sample is needed.

16. Personal contributions and conclusions

• The thesis proposed a critical study of the diagnostic and therapeutic management of obstructive sleep apnea syndrome. The work is made up of several studies, some retrospective and observational and others prospective and interventional.

• The data were collected from the observation sheets and operative protocols of patients admitted to the IFACF ORL Prof. Dorin Hociotă during the period 2014-2022 and the Institute of Aeronautical Medicine Gen. Dr. aviator Victor Anastasiu (INMAS) in the period 2018-2021. The studies were conducted on a group of 71 patients out of 77 who were admitted for surgery related to sleep apnea syndrome in the two medical institutions.

• The working hypothesis was to improve the diagnosis and treatment algorithm of obstructive sleep apnea syndrome due to the lack of a unified vision of how this pathology is viewed by different specialties. Perhaps it is precisely the interdisciplinary addressability of the OSA patient that has contributed to the lack of consensus regarding diagnosis and treatment.

• The aim of this thesis is to develop a diagnostic and treatment algorithm that reconciles the vision between specialties on how to manage OSA.

• Taking into account the results of the statistical tests undertaken in this work we can conclude that the Epworth daytime sleepiness scale can be used both as a screening tool for SOAS and as a tool for assessing the severity of sleep apnea syndrome, not just as a warning of the possible existence of this pathology.

• The interconnected and integrative approach of each case using the 3M diagnostic algorithm (Multimodal, Multilevel and Multistep) allows the adaptation of the next diagnostic step so that the patient can carry out the necessary consultations in order to make a final diagnosis that can later be addressed therapeutically.

• 3M (Multimodal, Multilevel and Multistep) treatment consisted of lifestyle changes, positional therapy, use of PAP devices and surgery.

• The multimodality within the treatment algorithm also consisted in the different types of surgical techniques and technologies used: surgery with cold instruments, coblation or radiofrequency, endoscopically assisted or classic approach.

• 3M treatment applied to patients in the study group reduced by approximately 50% the objective indices AHI, ODI and RDI measured at 3 months, 6 months and 12 months after the initiation of therapy. A statistically significant difference is found between the initial and the final level of AHI, so we can say that the 3M therapeutic algorithm had an effect and improved the condition of the patients.

• A considerable percentage of patients who underwent the simulated veloplasty maneuver by anchoring the soft palate with 2 Nelaton 8Fr probes showed relief of retropalatal obstruction. In contrast, this maneuver, as expected, proved ineffective in retroglossal obstruction.

• The use of the somnological file increases compliance with treatment, decreases the time until obtaining a final diagnosis, thus reducing waiting times, the economic burden on the health system and the need for exposure to the hospital environment, which is very important especially in a pandemic context.

17. Future research and development directions

• Because of the major impact on worsening cardiovascular and respiratory comorbidities as well as occupational safety, I believe that the main concern of clinicians and surgeons involved in the management of OSA should revolve around increasing diagnostic rates. In this sense, awareness programs similar to the "awareness" campaigns for breast, cervical and colon cancer could constitute models that reveal the real prevalence of the syndrome in the population. Since the application of subjective questionnaires that measure daytime sleepiness is simple and easy to understand, it is not invasive and does not require specialized training, the network of family medicine offices could perform an effective screening and detect cases in early forms. This would help reduce the economic burden on healthcare systems and increase job security.

• An important aspect of clinical utility of the present work is the development of a diagnostic and treatment algorithm doubled by the introduction of the tool called the "somnology file". The increased speed with which the cases were resolved and the high degree of satisfaction of the sleep record cohort leads me to believe that these results can be reproduced in the general population, and for this a prospective study with a larger cohort could confirm assumption.

18. References

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