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The cost-effectiveness of ambulatory vs laboratory based sleep services management of OSA

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Abstract
The Obstructive Sleep Apnea (OSA) is becoming a significant problem nowadays because it is associated with an increasing cardio-metabolic mortality. This disorder is increasing dramatically in the western world because it related to obesity. The cost-effectiveness ratio of OSA's diagnostic and therapeutic management is a strategic issue for health policy, which faces with recent international discussion involving the Western Health Systems. It has been shown that costs for simplified models used for diagnosis and outpatient care for OSA are minimal due to a more and more reduction of expenditure for both equipment and medical staff. This lack of investments and the utilization of portable and simplified monitoring devices could lead to incorrect diagnosis. This short review aims to offer discussion topics on the proper diagnosis and treatment of OSA in view of epidemiological / economic factors and results in terms of costs and social benefit of the disease.

Keywords: Obstructive Sleep Apnea (**OSA**); Epworth Sleepiness Scale **(ESS)**,cost-effectiveness (**CE**); Health Technology Assessment (**HTA**), Affordable Care Act (**ACA**); Teleservice **(TelaDoc);** Home sleep testing (**HST**); Continuous Positive Airway Pressure (**CPAP**); telemedicine interventions (**IT**)

Laboratory vs portable monitoring for the management of OSA

The growing concern that have been manifesting toward Obstructive Sleep Apnea (OSA), especially in the Western world, has led the focus on the more and more clear correlation between OSA and the reduced quality of life as well as the increment of cardiovascular and metabolic mortality (Edinger et al. 2016, 237-247) . The major OSA risk factor is obesity that is growing as the incidence of OSA (Romero-Corral et al. 2010, 711-719)**.** This condition often is underrecognized in hospitalized obese patients. A recent study, (Sharma et al. 2015, 717-723) has showed **to a** total of 636 obese patients admitted to medical center were classified as high risk Within 4 of discharge, 87% were shown to have OSA. The study shows significant under-recognition of OSA in obese hospitalized patients.

OSA (Epstein et al. 2009, 263-276) is characterized by daytime sleepiness, h**u**abitual snoring and at least 5 respiratory-obstructive events per hour of sleep, or >15 apneic events per hour in absence of symptoms. Other physical characteristics are highlighted in the pre-clinical test for assessing the probability of OSA, that include: BMI> 30, neck circumference >43 cm in men and 41 in women, daytime hypersomnolence measured with a self-assessment questionnaire, called the Epworth Sleepiness Scale (ESS) in which the cut-off is greater than 10.American Academy of Sleep Medicine guidelines suggests that portable monitors (nocturnal cardiorespiratory monitoring MCRN) may underestimate the seriousness of the ipopneic events compared to a complete polysomnography - Level 1 - that has been performed in a sleep laboratory The exponential increment of the OSA incidence, in particular in the general population from 40 to 70 years old, led to an unmet need to simplify

the OSA diagnosis using simplified diagnostic tests and to improve the treatment. In the past, the OSA diagnosis was performed into the sleep laboratory situated in the hospital, using polysomnography test, which required complex equipment and updated medical staff. Pietzsch et al. have performed a cost-utility study for the diagnosis of OSA. (Pietzsch et al. 2011, 695-709). This research group have assessed the cost-benefit ratio by comparing the three most used diagnostic / therapeutic strategies: a) overnight PSG along with a manual titration of the CPAP working pressure, in the sleep laboratory, b) split-night PSG along with manual titration of the CPAP working pressure; c) unattended portable monitoring (HST) with subsequent treatment with APAP (auto-titrating CPAP).

Another, recent study (Ayas, Pack et Marra 2011, 691-692) has considered 191 suspected OSA patients tested in advance using a preclinical test. Among them, more than half (56.5%) have manifested obstructive sleep apnea. Diagnosis of OSA was missed in 5.8% patients only, due to the lack of an accurate diagnosis from a specialist doctor of a sleep apnea.

The probability to obtain an accurate diagnosis using pre-clinical tests seems not to be influenced by the presence / absence of a specialist doctor in accordance with the severity of the disease. The authors concluded that OSA could be reliably identified using HST test regardless of pre-clinical test.

The increment of the need in diagnostic tools, (Aurora et al. 2016, 725-730; Huang et Rosenthal 2014, 1376-1379) have led the US to organize a home care model, a simplified Home Sleep Testing (HST) service company, refundable by the US insurance agencies, that deals with both diagnosis and therapeutic care of OSA patients. The services company called (Affordable Care Act) ACA, aims to provide high quality healthcare to OSA patients.

The ACA is gearing up towards a diagnostic model that focuses on the doctor-patient relationship (PCMH). In this home care model, the company puts at the center of this relationship a network of healthcare services where the primary cares are subsequently and rapidly integrated after being diagnosed. Basically, once the diagnosis and the treatment are determined, the Agency rapidly provides a home care technical support. This HST model is not inferior to other diagnostic / therapeutic models. This home care diagnosis and treatment is performed by health care professionals along with a consultation with a sleep specialist once. This approach reduces the economic costs of the medical staff and simplifies the delivery steps in providing the therapeutic equipment at home. This model results in a diagnostic improvement and in the increment of undiagnosed cases of OSA (Antic et al. 2009, 501-508; Davis, Abrams et Stremikis 2011, 1201-1203).

CPAP treatment: clinical and compliance

The treatment with the Continuous Positive Airway Pressure (CPAP) devices is the preferred treatment for severe OSA (Kushida et al. 2008, 157-171). The CPAP device consists of a nasal mask and / or oro-nasal through which an airflow is generated at continuous positive pressure by a compressed air blower system at low pressure. This established controlled pressure is designed to overcome the forces exerted by the soft tissues surrounding the upper airways. Because of this, treatment with CPAP is referred to as a 'pneumatic splint' (Donovan et al. 2015, 1323-1342).

Same studies have shown the benefits of treatment with CPAP in OSA as a mainstay of the treatment of symptoms such as snoring, daytime sleepiness, improvement of quality of life and of sleep as well as secondary depressive disorders (Cruz, Drummond et Winck 2012, 361-66; Donovan et al. 2015, 1323-42). Furthermore, it was shown that the treatment with CPAP reduces the risk of cardiovascular complications such as, stroke, heart failure, chronic ischemic heart disease and arterial hypertension (Barbé et al. 2012, 2161-2168; Gottlieb et al. 2010, 352-360).

Unfortunately, this therapy is burdened by a reduced compliance by patients that leading them to alternative therapies such as the positional therapy, surgical, orthodontic, that are able to give results superimposable to CPAP and stable in time in a well selected patient groups. The discovery of clinical phenotypes including genotypes with different pathogenic mechanisms has launched a new genetic and biomedical research field that will lead in the future to

new diagnostic and therapeutic strategies increasingly individualized (Malhotra, Orr et Owens 2015, 397-403)

An unmet need in literature is the lack of adherence / compliance to CPAP treatment. It should be evaluated, therefore, the possibility to develop technical / cultural tools in the form of educational / informational interventions able to improve adherence to treatment through an understanding of OSA and its complications. Several studies (Meurice et al. 2007, 37-42) have been conducted to assess the effect of educational / cultural intensive training in OSA and CPAP fields. These studies aim to obtain better results on the adherence of the patient. Interventions that have been conducted include the verbal-visual instruction by health professionals, the applications of the nasal and oral-nasal masks as well as the importance of the disease and its health effects (Jean Wiese et al. 2005, 171-174; Golay et al. 2006, 220-227) with standardized audiovisual presentations and practical demonstrations on performing standards treatments at home. Up to now, there is any "gold standard" training programs in literature that have steadily improved the adherence to CPAP treatment. Many of these clinical trials (Wickwire et al. 2013, 680-693) with double arm (control and study) have given controversial results. These latter studies were also criticized due to the higher level of education of the control arm respect to the study arm, compared to a normally routine care. Consequently, results on the adherence in the study arm has appeared worse. However, the majority of the experts still recommend to all patients that start CPAP, a high level of intensive instruction.

Health-care providers and CPAP: cost-effectiveness of models of care

The Health Technology Assessment is a multidimensional and multidisciplinary approach for the analysis of clinical, social, organizational, economic and legal implications in Italy. This approach undergoes a multi-dimensional evaluation such as the efficacy, safety, cost, and the social and organizational impact (Velardi et al. 2011).

Telemedicine interventions (IT) is a remote communication system of IT / medical data that is used to save time and reduce all the costs spent for managing a home care service for chronic diseases (Toma et al. 2014, 200-211; Park et al. 2014, 65-72). Not surprisingly, a number of clinical studies have been conducted to evaluate the effectiveness of telemedicine interventions (IT) on adherence to CPAP treatment. An expert IT technician has, in fact, produced some interesting data on health procedures on CPAP (Fox et al. 2012, 477-481).

The IT reports were transmitted and received from the individual CPAP home units onto the reference Provider center wirelessly therefore data from the study were collected and processed. Recorded data were represented by: a) loss of pressure in the mask, b) residual AHI c) number of hours of use (5 hours per night). Errors in performing the treatment were easily detected from the technician, who was able to call the patients the next morning through the central Provider and solve any problems about the low efficiency of the treatment. Result were seen after three months: the group assigned to the intervention in telemedicine had 1.88 hours / night of CPAP more compared to the control group with a lower residual AHI.

Another Spanish clinical multicenter randomized controlled trial (Isetta et al. 2015, 1054-1061) used telemedicine for studying economic and clinical impacts as well the improvement of the quality of life (QoL) with CPAP treatment compared to traditional follow-up with face-to-face doctor-patient controls. 139 patients were enrolled with sufficient knowledge of IT world. The follow-up included 3 controls at 1, 3 and 6 months to assess the quality of sleep, the side effects of treatment with CPAP and QoL. In this study were also detected the costs of the treatment and management from the beginning to the end of the study.

Results of the study were that a strategy based on telemedicine for follow-up of CPAP treatment in patients with severe OSAS, was as effective as a therapy performed in hospital in accordance with the gold standard, in terms of the compliance with CPAP and the improvement of the symptoms, with comparable side effects and satisfaction rates. The strategy based on telemedicine had a reduction of total costs in the transport service and productivity.

These new IT telemonitoring systems permit to save operating costs and manage several pa-

tients simultaneously (at least a hundred) using a single provider. However, they hint at possible medico-legal disputes. We try to address them. The first aspect to be defined is the fact that there is no standard of care for telemedicine at international level. Standards of care exist just for services for the individual but there are still not any e-Health practices. Medico-legal issues are: a) respect for personal privacy, b) inaccuracies of self-reporting of patients in data recording, c) the resolution limits of data to be recorded and the consequent delays due to failure / delayed treatment after the recording of data, d) failure of the systems that do not work correctly. In the US, there is a national society in telemedicine named TelaDoc (Gallegos 2015) which features a American National Committee to guarantee certification of electronic systems used in telemedicine, along with the production of evidence-based clinical practice guideline of registered data quality.

Another English multicenter randomized controlled study (McMillan et al. 2015, 1-188) assessed the clinical and economic aspects of the CPAP treatment in OSA elderly patients (PREDICT study). The study have showed that CPAP treatment in these patients (> 65 years) reduced the subjective and objective sleepiness similarly compared to younger patients. Secondary goals were determine the CPAP clinical efficacy, the cost-effectiveness ratio and the real usefulness of the treatment (model-based cost-effectiveness analysis) compared to alternative treatments with APAP / Bilevel / C FLEX (BSC).The QoL at 12 months of treatment was measured by the European Quality of Life-5 Dimensions (EQ-5D);

In elderly patients with OSA, CPAP treatment reduced the somnolence more significantly compared to treatment with APAP / Bi-Level / C FLEX (BSC) over a period of 12 months, improving the EQ-5D.In this recent clinical study (Tan et al. 2015, 525-535) approximately 50% of patients with OSA were intolerant to CPAP, this resulted in the selection of other therapeutic modalities such as surgical treatment. In order to evaluate the cost-effectiveness ratio in intolerant patients, this research group have compared three treatment strategies: (a) no treatment, (b) only CPAP and (c) CPAP followed by surgery (reconstructive palate-pharyngeal surgery (PPRS) or multilevel surgery (MLS]). Obtained results showed that CPAP therapy followed by PPRS (CPAP-PPRS) was the most profitable treatment compared to treatment with single CPAP and compared to the other strategies.

Another interesting prospective randomized controlled trial, published in 2010 by an Italian research group (Vicini et al. 2010, 14-20), have compared the efficacy of the ORL surgery, the maxilla-mandibular advancement (MMA) versus positive ventilation (auto-titrating) APAP. In conclusion, the study has shown that MMA can be a valid alternative therapeutic tool, not lower than the treatment with APAP.

Conclusions

In conclusion, there are many clinical studies that compared the efficacy between the diagnostic / ambulatory treatment versus diagnostic / hospital treatment. All these reports have elucidated that the management strategies for OSA are not clinically inferior to the hospital treatment and can produce similar results compared to the diagnostic / laboratory sleep treatment in hospital (Chai-Coetzer, Antic et McEvoy 2013, 605-615). However, we must point out some important limitations about HST when used in a long-term management strategy, because it can produce: **a**) limited capacity to diagnose sleep disorders other than OSA or non OSA syndrome related to metabolic disorders, neurological; **b**) the need to review / reevaluate the raw data that come automatically without performing a manual analysis of the nocturnal polygraphic tracings; **c**) uncertainties about the long-term use of this outpatient strategy on regards to the overall cost-effectiveness results compared to the hospital diagnostic plan that is based on the supervised polysomnography at 1st level.

There are also new emerging results in the literature that support the role of non-medical health professionals expert in sleep study such as nurses, care giver, IT / health care, who are able to manage the home care OSA in a cost-effective way. We still need of more long-term prospective studies that can evaluate the cost-effectiveness ratio, including direct and indirect costs of hospital management models versus models that take into account new qualified

non-medical personnel care. Finally, future knowledge in this area will come from the application of new technologies. Olivia J.et al (Walch, Cochran et Forger 2016, e1501705) to have shown that the sleep wake rhythm is changed from a social plan. They used smartphone app that have developed, ENTRAIN, accurately collects data on sleep habits around the world. This work better defines and personalizes "normal" sleep, produces hypotheses for future testing in the laboratory, and suggests important ways to counteract the global sleep crisis Moreover, we use mobile technology to collect a massive data set at essentially no cost. In analyzing these large data sets, mathematical modeling will be key to generating useful predictions from the unstructured bulk collection

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