The Importance of Mask Type and Mask Materials in Sleep Apnea Patients

NICOLETA STEFANIA MOTOC[1], MILENA ADINA MAN[1]*, SORIN IOAN TUDORACHE[2], ELENA RUSU[3], CONSUELA MONICA BRAILESCU[4], BEATRICE MAHLER BOCA[5], ANDRADA URDA CAMPEAN[6], CARMEN MONICA POP[1]

[1]University of Medicine and Pharmacy Iuliu Hatieganu, Medical Specialties Department, 8 Victor Babes Str, 400000, Cluj-Napoca, Romania

[2]Titu Maiorescu University, Faculty of Medicine, Anatomy Department, 22 Dambovnicului Str, 031593, Bucharest, Romania

[3]Titu Maiorescu University, Faculty of Medicine, Biochemistry Department, 22 Dambovnicului Str, 031593, Bucharest, Romania

[4]Carol Davila University of Medicine and Pharmacy, Medical Rehabilitation Department, 8 Eroii Sanitari Bvd, 020021, Bucharest, Romania

[5]Carol Davila University of Medicine and Pharmacy, Pneumology Department, 8 Eroii Sanitari Bvd, 020021, Bucharest, Romania

[6]University of Medicine and Pharmacy Iuliu Hatieganu, Medical Education Department, 8 Victor Babes Str, 400000, Cluj-Napoca, Romania

Mask is an important prognostic factor in patient's compliance to positive airways pressure. As there are a lot's of factors that contribute to a good interface choosing the right mask remains a challenge. The aim of this study was to evaluate the importance of mask and mask materials in treatment compliance to positive airway pressure in a sample of Romanian patients hospitalized for sleep study. Other factors that may have influence on the compliance were also evaluated (severity of sleep apnea, the presence of symptoms, comorbidities and the type of device used (CPAP or BiPAP). 107 patients with newly diagnosed sleep apnea were included. They received positive airways pressure treatment with nasal or oronasal mask depending on their own preference and tolerance and they were followed for one year. After one year 70% of 107 patients were still on positive airway pressure treatment (CPAP or BiPAP). There seemed to be no difference between the two masks when looking at the whole group. When analyzing the subgroups, however there seemed to be a preference for the nasal mask in patients who were treated with CPAP and oronasal mask in patients treated with BiPAP, suggesting that the associated conditions (COPD) might play an more important role than the mask itself. The materials did not influence the compliance.

Keywords: sleep apnea, mask type, positive airway pressure

Sleep apnea syndrome is a condition characterized by recurrent episodes of partial and complete upper airway collapse during sleep resulting in sleep fragmentation and intermittent hypoxemia. Depending on the cause it can be obstructive (obesity, abnormalities of upper airways, muscle relaxation etc.) or central (stroke, cardiac failure, drugs) [1]. Obstructive sleep apnea is a frequent comorbidity in chronic obstructive pulmonary disease (COPD) resulting in COPD-OSA overlap syndrome [2-4]. Gold standard treatment of patients with moderate to severe OSA is the application of continuous positive airway pressure (CPAP) during sleep. When COPD is present, sometimes, non invasive ventilation is required: bi-level positive airway pressure (BiPAP). For example, in patients with diurnal hypercapnia or when the pressures are too high and the patient do not tolerate them [1,2]. Compliance to the treatment is a major factor in treatment response [5]. A good compliance is considered when the patient uses CPAP more than 4 hours a night and BiPAP more than 5 hours per night, over 80% of treatment time [6-9]. The adherence to treatment is very variable (46- 80%) and one of the most important prognostic factors is mask type [7-9]. Currently there are a lot of models available: nasal mask, oral mask, full face mask, nasal *pillows* or prongs mask and hybrid masks. They can be used in both CPAP and BiPAP treatment [9]. Nasal or pillows mask are associated with a better compliance and are the most used in sleep apnea patients [2, 9]. The mask is very important as pressure-related skin and tissue necrosis are still very frequent and reduces patient's compliance to treatment. Therefore the mask should be made from soft, malleable material to facilitate customized usage and correctly fit over the individual's nose and mouth. CPAP masks are made of plastic and/or silicone or gel-like materials. Some are made of fabric and other hybrid materials. Most of them are made from silicone. In some cases allergies to silicone have been described. The aim of this study was to evaluate the importance of mask and mask materials in treatment compliance to positive airway pressure in a sample of Romanian patients hospitalized for sleep study. Other factors that may have influence on the compliance were also evaluated (severity of sleep apnea, the presence of symptoms, comorbidities and the type of device used (CPAP or BiPAP)

Experimental part

Material and methods

This is a prospectively cross sectional study.

Study population

Were enrolled all patients, over 18 years old that consecutively presented for sleep study in *Leon Daniello* Clinical Hospital of Pulmonology from Cluj Napoca, Romania in one year from January 2018 to December 2018. Inclusion criteria: all patients that had indication or recommendation for cardiorespiratory polygraphy and had an apnea hipopnea index (AHI) > 15. Exclusion criteria: patients that after diagnosis did not qualified for positive airway pressure, patients that had respiratory failure requiring long term oxygen therapy, patients with severe cardiovascular comorbidities, patients that were already been diagnosed with sleep apnea and were currently being treated or treated before but gave up treatment and patients

*email: manmilena50@yahoo.com

All authors have equal contributions

that did not have a valid polygraphy [10]. The patients were followed for one year, with periodical follow ups at 1, 3, 6 months and 1 year. At every follow up their compliances was checked using the codes from the device (www.intellipap.com). Those who did not meet the criteria of a good compliance were asked verbally the reason and the reason was noted by the same physician that did the initial evaluation. All patients signed an informed consent for participating in the study. The study was approved by the Ethics Committee of University of Medicine and Pharmacy Iuliu Hatieganu, Cluj Napoca no 232/05.07.2019.

Study equipment

Anamnesis and physical examination were performed by a physician and demographic data were recorded. All patients had an overnight cardiorespiratory poligraphy *(Nox*-T3 device, ResMed) performed. All polygraphy recordings were manually scored. The recording was considered valid if it had at least for hours of continuous recording and had all the signals working, without interruption during that period. The titration was done, depending on the indication, with CPAP (DV 54 Autoadjust CPAP, ResMed) OR BiPAP (DV 57AutoBilevel, ResMed). The pressures were established depending on patient tolerance. The masks used were nasal mask or oronasal mask: FlexiFit407 and F&P Simplus (Fisher and Paykel). After diagnostic night all patients that had sleep apnea diagnosis, requiring positive airway pressure treatment, were explained the treatment. A mask was given to the patient and he had to choose nasal or oronasal depending of his preference. Afterwards the pressures were set up considering titration results and patients own tolerance.

Statistics analysis

Data was analyzed using SPSS v.2 software. Quantitative data was described using mean ± standard deviation, minimum, maximum, median and the interval between 25th percentile (Q1) and 75th percentile (Q3). Qualitative data was described using counts and percentages; the link between two qualitative data was tested using the Chi2 test with a significance level of 0.05.

Results and discussions

107 patients that consecutively presented with the suspicion of sleep apnea were recruited. Patients demographic data are are shown in table 1. Most of them were male, with a mean age of 58.22 ±11.7 years old, with stage II obesity (BMI= 37.53±7.58 kg/m^2). The majority was having characteristics of metabolic syndrome: arterial hypertension, diabetes, dyslipidemia (table 2). The most frequent anomalies in the ear-nose-throat region were septum deviation and chronic rhinitis. There were 2 women with polycystic ovary syndrome (PCOS) sent by the endocrinologist. Regarding the treatment 25.23% (27/107) patients did not accept the treatment at all. Some of them refused even the titration, while the rest they did not acquired the device after discharge. 4.67% (5/107) have quit the treatment after several months. One patient lost weight (20 kg). He refused to repeat the polygraphic evaluation being convinced that he does not need the device anymore and the rest of them from financial reasons. However the great majority of patients used the device the whole period: 48.59% (52/107) used CPAP and 21.49% (23/107) used BIPAP. As shown in table 3 most of patients preferred the nasal mask. There was a statistically significant link between the use of a mask type and the type device patients on CPAP preferred oronasal mask, while patients on BiPAP preferred oronasal mask (p= 002) (see table 3). Masks composition was the same for both oronasal and nasal mask: polycarbonate for the frame, silicone elastomer for the cushion and nylon/spandex, polycaprolactam and rayon acetate satin for the headgear. We did not notice any allergic reaction or intolerance to any of these products. Few patients had pressure related skin lesions after first night, but disappeared in the following days after a proper adjustment of mask and headgear. As expected the more symptomatic the patient, more compliant he was at the treatment.

70% out of 107 patients evaluated for sleep apnea in a Teaching Pulmonology Hospital from Cluj Napoca, Romania had a good compliance to positive airway pressure treatment during 1 year follow up. Good compliance was defined as the use of CPAP more than 4 hours a night and BiPAP more than 5 hours per night, over 80% of treatment time [2, 6- 9]. Both nasal and oronasal mask were used in the same percentage in sleep apnea patient. When analyzing the CPAP group vs BiPAP group, however we see a preference for the nasal mask in the CPAP group (59.6% vs 40.4%) and for oronasal mask in the BiPAP group (69.6 % vs 40.4%). Although still a very challenging subject, several studies have shown that sleep apnea patients treated with CPAP prefer nasal mask [11-14]. Nasal mask have less contact with the face compared to oronasal masks and may benefit the patients by minimizing side effects, especially pressure related skin lesions. Also there are fewer leaks. However they are less tolerated when higher pressures are needed. This might be the reason why patients who needed BiPAP preferred oronasal mask. These patients are patients with COPD – OSA overlap syndrome, generally more obese and requiring higher pressures [1,2,6,15]. So it's in fact the underlying disease more than the device itself that dictates the mask type. 30 out of 107 patients had COPD-OSA overlap syndrome. Educational, supportive and behavioral interventions are also very important, helping people to recognize the need for regular and continued use of positive

	N	Mean ± SD	Median (Q1 - Q3)
AHI (/hour of sleep)	107	38.39 ± 21.63	25 (33.9 - 40)
ODI(/hour of sleep)	107	38.22 ± 23.58	25 (32.2 - 45)
Age (years old)	107	58.22 ± 11.7	51 (61 - 67)
Height (cm)	107	169.86 ± 9.55	164 (170 - 176)
Weight (kg)	107	108.39 ± 23.82	92 (107 - 120)
BMI (kg/m2)	107	37.53 ± 7.58	32.61 (36.68 - 41.52)
PI (pack a year index)	107	17.42 ± 16.72	0 (15 - 30)

Table 1
PATIENTS CHARACTERISTICS

		Frequency (n=107)	Percent (%)
Gender	Male	74	69.2
	Female	33	30.8
Environment	Rural	29	27.1
	Urban	78	72.9
COPD	Absent	70	65.4
	Present	37	34.6
Diabetes	Absent	79	73.8
	Present	28	26.2
PCOS	Absent	105	98.1
	Present	2	1.9
Hypotiroidism	Absent	99	92.5
	Present	8	7.5
Arterial Hypertension	Absent	57	53.3
	Present	50	46.7
Dyslipidemia	Absent	56	52.3
	Present	51	47.7
Septum deviation	Absent	96	89.7
	Present	11	10.3
Chronic rhinitis	Absent	98	91.6
	Present	9	8.4

Table 2
PATIENTS COMORBIDITIES

			BIPAP	CPAP	Total
MASK	nasal mask	Count	7	31	38
		%	30.4%	59.6%	50.7%
	oronasal mask	Count	16	21	37
		%	69.6%	40.4%	49.3%
Total		Count	23	52	75
		%	100.0%	100.0%	100.0%

Table 3
DEVICE AND MASK TYPE

airways pressure. Cognitive behavioral therapy in sleep apnea patients has been proving to lead to the largest increases in average machine usage [16, 17]. In our hospital the patients discuss mask and device related issues with the treating physician and medical representative that provides the device. There are not specialized nurses, respiratory therapists or physiologist that could help them in giving more information or help with particular problems. A large number of our patients did not accept the treatment at all (27 out of 107) and 7 of them refused even the titration night. The rest did not accept the treatment due to the fact that they had to pay for it. As sleep apnea syndrome often co-exists with other chronic conditions such as hypertension, dyslipidemia, depression, diabetes, and coronary artery disease, there is also a individual adherence to positive airway pressure treatment correlated with adherence to other medical treatments [17-22]. The more compliant is to other treatment most likely he will be compliant ro positive airway pressure also. Particularity of this sample is the financial cause as a lack of compliance; in Romania the insurance companies do not pay the treatment so the patients have to support everything including the mask that is a supplementary cost. Therefore he will choose a cheaper one even if it's not what feels more comfortable. The issue of patients having to pay for his treatment remains a burning issue as it has already been emphasized before in other studies [23, 24]. There are companies that, in certain conditions, give a

nasal mask for free, this could be a bias in our study although our results are similar to other data from then literature.

Limitations of the study: it's single center study, the sample it's too small, therefore some data cannot be generalized. The gold standard for diagnosis sleep apnea remains overnight polysomnography and our patients have cardiorespiratory polygraphy. Despite it's obvious limitations our study emphasize the importance of mask type in different sleep apnea patients. If CPAP is necessary a nasal mask is preferred and associated with a good compliance, however in patients that have COPD that requires non invasive ventilation oronasal mask would be preferable as higher pressures are needed. The lack of national assurance company reimbursement remains an important factor in low compliance to the treatment in some countries, in ours included.

Conclusions

Mask type is an important parameter in a good compliance to positive airways pressure treatment. In our study, there seems to be no difference between using nasal or oronasal mask when considering positive pressure in general. However patients treated with CPAP seem to prefer nasal mask, while patients treated with BiPAP seems to prefer oronasal mask, but this is related to the underling condition more than to the mask itself. There were no adverse events related to mask materials and they seemed to have been well tolerated by the patients.

References

1.SIMMONDS. A., de BACKER. W., ERS Handbook of Respiratory Sleep Medicine, 2012

2.McNICHOLAS. WT., Chest **152**, no.6, 2017, p:1318-26

3.JIMBOREAN, G., SZASZ, S., SZATHMARY, M., CSIPOR, A.,, ARGHIR, O.A., NEMES, R.M., POSTOLACHE. P., IANOSI. E.S., Rev. Chim. (Bucharest), **69**, no 4, 2018, p.1014-1017.

4.BUDIN, CE., MAIEREAN, AD., IANOSI, ES., SOCACI, A., BUZOIANU, A.D., ALEXESCU, T.G., OLTEANU, M., RUSU, E., MOLDOVAN, C.A., NEMES, RM., Rev.Chim.(Bucharest), **70**, no. 2, 2019, p. 449-454

5.IANOSI, E.S., DANTES, E., CSIPOR, A., SZATHMARY M., SOCACI A., RUSU, E., NEMES, R.M., Rev.Chim.(Bucharest), **69**, no.10, 2018, p:2725-2727.

6.WEAVER, TE., GRUNSTEIN, RR., Proc Am Thorac Soc. **5**, no.2, 2008, p:173–8.

7.KRIBBS, NB., PACK, AI., KLINE, LR., SMITH, PL., SCHWARTZ, AR., SCHUBERT, NM., et al. Am Rev Respir Dis. **147**, no 4, 1993, p: 887–95.

8.PEPIN, JL., KRIEGER, J., RODENSTEIN, D., CORNETTE, A., SFORZA, E., DELGUSTE, P., et al. Am J Respir Crit Care Med. **160**, no. 4, 1999; p:1124–29.

9.WEAVER, TE., Curr Opin Pulm Med., **12**, no. 6, 2006, p:409–13.

10.TEREANU, C., BAILI, P., BERRINO, F., MICHELI, A., FURTUNESCU, FL., MINCA, DG., SANT, M., European Journal Of Cancer Prevention **22**, no. 3, 2013, p:199-209

11.MING, T., TERENCE, A., SHARON, L., et al. Sleep.; **34** no.7, 2011, p: 951-5.

12.MEURICE, JC., PAQUEREAU, J., DENJEAN, A., PATTE, F., SERIES, F., Eur Respir J, **11**, 1998, p:1121-7.

13.MARRONE, O., INSALACO, G., BONSIGNORE, MR., ROMANO, S., SALVAGGIO, A., BONSIGNORE, G. Chest, **121**, 2002, p:759-67.

14.MORTIMORE, IL., WHITTLE, AT., DOUGLAS, NJ. Thorax; **53**, 1998, p:290-2

15.VALENTIN,A.,SUBRAMANIAN,S.,QUAN,SF.,BERRY,RB.,Parthasarathy, S., Sleep, ;**34**, 2011, p: 801–6.

16.DAMJANOVIC,D.,FLUCK,A.,BREMER,H.,MULLER-QUERNHEIM,J.,IDZKO,M., SORICHTER,S..EurRespir J.;**33**, 2009,p: 804–11.

17.BAKKER, JP., WEAVER, TE., PARTHASARTHY, S., et al Chest.; **18**, 2019, p: 1578- 94.

18.DIEFFENBACH, P., BRAVATA, D., FERGUSON, J., et al. Chest.;**142**, 2012,A142

19.PLATT, AB., KUNA, ST., FIELD, SH., et al. Chest.;**137**, no.1, 2010, p:102-108.

20.TANTU, M.M., MAN, G.M., ROGOZEA, L.M., DOMNARIU, C.D., PLESA, F.C., TRASCA, D.M., COTOI, B.V., STOICA, L.E., NICOLAE, C., NEMES RM. Romanian Journal Of Morphology And Embryology, 59, no.3, 2018, p: 895-902

21.TANTU, M.M., MAN, G.M., PAUNESCU, A., PLESA, C.F., NICOLA.E, C., ROGOZEA, LM., BISOC, A., MOSTAFA, M.F., NEMES, R.M., Rev.Chim.(Bucharest), **70**, no.4, 2019, p.1307-1310

22.***Adherence to long-term therapies. World Health Organization website.http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf. Accessed March 29, 2018

23.TARASIUK, A., REZNOR, G., GREENBERG- DOTAN, S., et al. PLoS ONE.;**7**, no.3, 2012, p:e33178

24.MIHALTAN, F., DELEANU, O., MUNTEANU, I., et al..Adherence to CPAP- eternal issue. Pneumologia.; **61,** no.2, 2012, p:108-12

Manuscript received: 08.06.2019