Experiment of Intranasal Synthetic Filter for Prevention of Suspended Particulated Matter: Rhinomanometric Evaluation

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Abstract

The experimental study of intranasal synthetic filter with stent was tried to decrease suspended particulate matter for human respiratory tract. Facial mask or surgical mask were evaluated. Nasal vestibular size in Thai adults was estimated. Different kinds of stents and filters were used. Standard anterior rhinomanometry was the proper objective method to test nasal air flow resistant of stent and filter. Nasal obstructive symptom correlated well with rhinomanometric results. One layer of outer and inner face mask at each end of the cylindrical silicone stent was the suitable device. There were no complications or side effects. This personal protective device was cheap and available. The filtration efficacy should be tested in a general population during a highly air-polluted period.

In a critical air pollution condition, all effords were tried to improve the environment such as lead in the fuel, catalytic converter for vehicle exhaustion, industrial waste products or dust from construction(1). The amount of suspended particulated matter (SPM) or toxic substances increase dramatically and progressively even after vigorous long-term management(2,3). Concentration of hazard substances in a large city are in the danger range(4,5). The short-term solutions that should be managed immediately are very important. Filtration of these substances from the inhaled air could be one of the best solutions(6). Facial mask, half mask or surgical mask are used with discomfort problems, air leakage between the face mask and patient's face. If the facial mask was sealed around the nose, the patient felt severe nasal obstruction (7-10). Intranasal filtration by synthetic material should be one of the alternatives to provide clean air for the human respiratory tract and decrease air pollution hazards in the population, especially from SPM(11,12). This project was designed to study the efficacy of different types of intranasal synthetic filters and stents by rhinomanometric evaluation(13,14). Human safety and cost-effectiveness are considered.

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MATERIAL AND METHOD

The experiment was conducted from July 1994 to August 1996 at the Otolaryngology Department, Ramathibodi Hospital, Mahidol University, Bangkok. This was pilot study phase I for a prophylactic trial in humans. The project design was before and after experiment without a control group. All the tests were done by the investigater.

1. Face mask evaluation

The face mask or surgical mask composed of a middle layer of cotton, an outer filter layer and an inner filter layer. When examined under light microscopy, the middle layer was of fine, high solidity material. The outer and inner layers were of coarse and loosely packed material. The anesthetic mask was sealed around the nose and mouth of the subject. Normal nasal breathing through the anesthetic mask was done with different layers of face mask filters attached at the other end. Subjective nasal obstruction symptom (NOS) was recorded when compared with the absence of the filter in the same subject. (Table 1)

Table 1. Evaluation of different layers of face mask filter and nasal obstruction symptom (NOS) by anesthetic mask.

Filter	NOS
none	none
1 paper, 1 outer, 1 inner	severe
1 paper, 1 outer	severe
1 paper, 1 inner	severe
1 paper	severe
2 outer, 2 inner	severe
1 outer, 1 inner	mild
1 outer	mild
1 inner	mild

2. Nasal vestibular size estimation

Nasal vestibular size was measured in order to select the proper diameter of the intranasal synthetic stents. The test was done in 21 Thai adults, 12 males and 9 females with a mean age of 36.9 years old, range 18-60 years old. The criteria for patient selection were :

1. no previous nasal surgery
2. no history of severe accident or trauma of the face
3. no deformity of the external nose or septal deviation
4. no inflammation of the nasal cavity such as rhinosinusitis or vestibulitis.

The nasal vestibular size was measured by balloon catheter for the heart valuvulotomy. This balloon was better than the foley catheter due to its cylindrical shape and gradual increase in diameter when fully inflated. The balloon was placed in the nasal vestibule and inflated until the patient felt mild discomfort. The balloon was removed and the maximum diameter was measured with a Wernier ruler. The measurements were done three times on each side of the nasal vestibule. The average value is shown. (Table 2)

Table 2. Nasal vestibular size.

Mean diameter	1.7 cm
Range diameter	1.6-1.8 cm
Mean right nose	1.7 cm
Mean left nose	1.7 cm
Mean of male	1.7 cm
Mean of female	1.7 cm

Table 3. Dimension and consistency of various intranasal synthetic stents.

Stent No.	Diameter outer (cm)	Diameter inner (cm)	Cross-sectional area (cm^2)	Consistency
1	1.7	1.6	2.01	Hard
2	1.3	1.2	1.13	Hard
3-16	1.1	0.9	0.64	Soft

Table 4. Filter character of each stent.

Stent No.	Filter
1.	none
2.	none
3.	none
4.	face mask inner filter, 1 layer, at one end and face mask outer filter, 1 layer, at other end
5.	face mask inner filter, 1 layer, outward
6.	face mask inner filter, 1 layer, inward
7.	face mask outer filter, 1 layer, outward
8.	face mask outer filter, 1 layer, inward
9.	face mask outer and inner filter, 2 layer, one end, outward
10.	face mask outer and inner filter, 2 layers, one end, inward
11.	face mask outer and inner filter, 4 layers, both ends
12.	cotton
13.	sponge
14.	cigarette filter, 0.25 cm in length
15.	cigarette filter, 0.5 cm in length
16.	cigarette filter, 1.0 cm in length

3. Intranasal synthetic stent selection

The intranasal synthetic stents were used to:

1. maintain the dimension of the intranasal synthetic filter material
2. prevent movement of the filter during respiration
3. avoid nasal secretion on the filter surface

From the nasal vestibular size estimation in Table 4, the maximal nasal stents diameter could not be greater than 1.7 cm. All of the stents were of a hollow cylindrical shape. Stent No 1 was hard plastic, the largest outer diameter and "C" letter appearance were compressible. The stent was applied to dilate the nasal vestiblule with pressure. The patient felt discomfort with stent No 1. Stent No 2 was hard plastic and just fitted the nasal vestibule without discomfort. Stents No 3-16 were soft medical grade silicone tubes which loosely occupied the nasal vestibule without discomfort. The length of all stents was about 0.8 cm in order to avoid the nasal valve area which was 1.5 cm from the anterior nasal rim. Too long a stent created more pressure and discomfort. The thickness of each stent wall was 1.5 to 2.0 mm. The cross-sectional area was calculated from the inner diameter of each stent. (Table 3)

4. Intranasal synthetic filter application

Different kinds of intranasal synthetic filters were used. (Table 4) Stents No 1, 2 and 3 had no filter. The filter might be attached at each end with adhesive tape around the outer surface or put inside stents No 4-16. A face mask or surgical mask composed of one layer of cotton sheet between the outer and inner layers of the filter paper. Stent No 4 had an outer filter at one end and an inner filter at the other end. One layer of inner filter was sealed at one end of stents No 5 and 6. One layer of outer filter was sealed at one end of stents No 7 and 8. Stents No 9 and 10 were sealed with an outer and inner filter at one end of the stents. The outer and inner filters (double layers) were sealed at both ends of stent No 11, totally four layers of filter.

Stents No 5, 7 and 9 faced the filter side outward when performing the test so the filter side was close to the test machine. Stents No 6, 8 and 10 faced the filter side inward when performing the test so the filter side was near the nasal cavity.

There was no filter paper at both ends of stents No 12-16. Cotton in stent No 12, sponge in stent No 13, cigarette filter in stents No 14, 15 and 16 were packed loosely within each stent. Filter material inside the stents did not move with respiratory phases. All of the filter material was examined under light microscopy prior to the rhinomanometric test. Each type of filter material was composed of a different diameter of fiber and

solidity. Paper or middle layer of the face mask was not used due to its high resistance to nasal air flow. (Table 1)

5. Air-flow and rhinomanometer

NR-2 rhinomanometer (Mercury Electronic, Ltd; Pollok Castle Estate, Newton Mearns, Glasgow, Scotland) was used to test the airflow through the nasal passage. The test was controlled by a personal computer with specific software. The accuracy of the NR2 was calibrated intermittantly with FP1. The accessories were anesthetic mask, connector, monitor and printer[13]. Anterior standard rhinomanometry was performfed due to its reliability and objectiveness[14]. The experiment was done in the same subject and period to avoid subject variation. Each kind of stent and filter was tested three times, the average value was calculated. (Table 5)

The rhinomanometric test was done without stent and filter and the result was used as the control value. The tests in stents No 1, 2 and 3 were used to compare the different diameters and composition of stents without filters. Stents No 4-11 were tested for the effect of only the filter at one or two ends of the stents, without filter material inside. The tests in stents No 12-16 were done with different filters inside the stents, without filter paper at each end. The filters in stents No 5, 7 and 9, which were close to the rhinomanometric machine were tested to compare with the filters in stents No 6, 8 and 10, which faced the filter far from the machine.

RESULT

The evaluation of different layers of the face mask filter and nasal obstruction symptom (NOS) was done by the anesthetic mask. (Table 1) The middle layer or paper layer of the face mask created the most resistance to nasal airflow. The air flow through both outer and inner was the same as one layer of the face mask and the patient felt comfortable. The two layers of outer and two layers of inner layers, totally four layers of filter were not suitable. (Table 1) When the patient uses the face mask, nasal air flow should pass between the face mask and the face. The filtration efficacy of the face mask for suspended particulate matter (SPM) or other air pollution substances was questionable.

From Table 2, the range diameter of nasal vestibular size in Thai adults was 1.6-1.8 cm and the mean was 1.7 cm. The mean of the right side was 1.7 cm and 1.7 cm on the left side. The mean of nasal vestibule in males was the same as in females. The proper diameter of the nasal stent, including thickness of the filter material and adhesive tape around the outer surface of the stent

Table 5. Rhinomanometric results and nasal obstruction symptom (NOS) of intranasal synthetic stents and filters.

Filter & stent	Inspiration (cm H_2O/L/sec)	Expiration (cm H_2O/L/sec)	Different both nasal (%)	NOS
None	0.208	0.182	63	none
No. 1	0.194	0.193	74	none
No. 2	0.171	0.161	49	none
No. 3	0.185	0.184	56	none
No. 4	0.225	0.192	47	mild
No. 5	0.247	0.224	42	moderate
No. 6	0.295	0.280	32	moderate
No. 7	0.249	0.226	47	moderate
No. 8	0.247	0.231	115	moderate
No. 9	0.217	0.177	32	mild
No. 10	0.216	0.187	33	mild
No. 11	0.359	0.355	99	severe
No. 12	0.864	0.783	48	severe
No. 13	0.704	0.724	42	severe
No. 14	1.089	1.136	83	severe
No. 15	1.463	1.405	160	severe
No. 16	2.271	2.458	83	severe

should not be greater than 1.7 cm. The stent and filter No 11 had a maximum diameter of 1.4 cm. When stent No 3 was occluded, the air could not pass around the stent.

The rhinomanometric results in Table 5 are standard anterior type. The none-stent test value was used as the control group. Dilatation of the nasal vestibule under pressure and increased cross-sectional area of the vestibule by stent No 1 created nasal airway resistance that was not different from stent No 2 that just fitted, or stent No 3 that was loosely packed in the nasal vestibule. The test results were not different with filters in stent No 5, 7 and 9 which faced outward and were close to the test machine and the filter paper in stents No 6, 8 and 10 which faced inward toward the nasal cavity. One layer of filter at both ends of stent No 4 had resistance that was lower than one layer filter at one end of stents No 5-8. The two layers of filter at one end of stents No 9 and 10 also yielded lower air flow resistance than one layer filter of stents No 5-8. The increased airflow resistance was due to the vibration of one layer filter with respiration phase in stents No 5-8.

Two layers of filter paper at both ends of stent No 11 was not proper due to high air flow resistance and severe nasal obstruction. The cotton and sponge in stents No 12 and 13 created very high resistance for the nasal airway and the patient felt severe discomfort. This might be from the solidity of the filter material which was very difficult to adjust. If cotton or sponge was packed too looseby in the stent, the materials moved in and out with the respiratory phase and the rhinomanometry failed. The high resistance from the cigarette filter within stents No 14-16 were due to high solidity of the material and the patient felt severe discomfort. (Table 5)

DISCUSSION

Intranasal synthetic filter with stent was proposed to decrease SPM to the respiratory tract. This has not been reported in the English literature. Thailand standardization for outdoor SPM concentration was 0.33 mg/cu m/24 hour. In Bangkok, the SPM concentration was within standard 0.01 mg/cu m in 1982 but from 1984 to 1989 it was above standard. The maximal dust concentration of Bangkok in 1992 was 647.69 +/- 280.72 mcg/cu m. The mean dust concentration was 504.16 +/- 101.18 mcg/cu m. Policeman got dust 5.2 times more than office workers[2]. Examples of severe air pollution problems were City of Dorora in 1848, Meuse in 1930, Berlin and Bitterfield in 1971.

Air pollution included SPM and vapour. Gas could not be destroyed or filtered. The source of air pollution came from diesel vehicles 40 per cent, dust 40 - 50 per cent and industry 10 per cent. The particle size was smaller than 10 micron with a range between 0.6-1.0 micron and 5.0-7.0 micron. 60 per cent of the particles were smaller than 10 micron. Hypersensitivity pneumonitis from organic dust and mold which was smaller than 3-5 micron could occur[3,4]. The cumulative delivery of the agent was the concentration of the agent X times exposure[12].

The intranasal synthetic filter should be non-toxic, compressible with nasal vestibule adaptation, efficacy for filtering, reusable or disposable and cost-effectiveness. (Table 4) The face mask, half mask or surgical mask was selected in this experiment due to its popular personal protection in the general population for air pollution control. The leakage of SPM around the face mask came from its high nasal air flow resistance of the middle layer (Table 1). The filter for SPM might be cotton, sponge, cigarette filter, membrane filter, gauze oiled-cloth, stainless steel, fiberglass, foam, nylon mesh, electrically charged fiber such as resin-wool or Hansen filter, electret fiber, mixed fiber and fine fiber polycarbonate or polypropylene. Usually the filter had 78-80 per cent efficiency. The leakage penetration or LP_{en}(%) of the filter might be calculated by the formula[15-17]:

$$LP_{en} = 90 - 9.8d_a - 7.8Inp - 1.5(Inp)^2 - 1.4d_a(Inp) - 0.15\, d_a(Inp)^2$$

d_a = particle diameter 0.1-12 um

P = pressure drop instantaneously

The filter penetration or FP_{en} calculation formula might be:

$$FP_{en} = (3.49 + 0.014WR)\, Exp[-d_a(3.10+0.00127WR)]d_a \quad 0.1<or> 1um$$

$$= (0.2158 + 0.00025WR)\, Exp[-d_a(0.2192+0.000645WR)]d_a \quad >1.0\ um$$

WR = work rate in kg-m/min

The efficacy of each filter from the above two formula depended on the diameter of the particle, pressure drop across the filter and work rate of the subjects. The air-flow was velocity X pressure drop[18]. The steady state flow of respiratory phase was 16 litre/min and cyclical flow was 30-52 litre/min. The inspiratory negative pressure was 10 mm H_2O and duration of 2 sec. Expiratory positive pressure was 8 mm H_2O and duration of 3 sec. Respiration rate was 10-18 /min[19,20].

The intranasal synthetic stent size was selected according to the nasal vestibular size estimation (Table 2 & 3). The stents should be non-toxic, non-irritant in order to fit the nasal vestibule without discomfort or collapse. Usefullness of the stents was to prevent the movement and wetness of the filters. Medical grade silicone tube was used due to its availability and cost effectiveness. The hard plastic was too rigid to apply in the nasal vestibule.

The rhinomanometic test was objective evaluation for nasal air flow[13]. The subjective symptom of nasal obstruction (NOS) correlated well with the rhinomanometric value. Normal value of standard anterior rhinomanometry in Thai adults has been reported[14]. The value was 0.268 +/ - 0.088 for inspiration, 0.265 +/- 0.098 for expiration with 0.237 - 0.299 and 0.232 -0.298 of the confidence intervals. The goal was to create air flow through the nasal model or patient nostril with minimal resistance when compared with the normal value. Stents No 4, 10 and 11 were the proper solution. (Table 5) One layer of filter paper at both ends of stent No 4 should be the best method. This model was suitable for estimation of the deposition of SPM on each layer of the filter. The inner layer of the filter in stent No 4 was also used to prevent humidity from the respiratory tract. Too much humidity could decrease the efficacy of the filter material.

The total resistant change in the nasal airway might be due to :

1. Inner cross-sectional area of the stent was an important factor. If the cross-sectional area of the nasal cavity is less than 0.4 cm^2, there is 97 per cent change of mouth breathing. An example in a 15 year old patient, the minimal nasal airway size should be 0.6 - 0.7 cm^2[21,22]. The cross-sectional area of the stent and filter in this study was 0.64 - 2.01 cm^2. The increased diameter of the stent which was larger than 0.64 cm^2 did not benefit for nasal air flow. (Table 3 and 5)

2. Thickness or length of the filter material in each stent or filter paper at both ends of the stent should be of concern. The best stent and filter was No 4. Stent No 11 had too much airflow resistance. Stent No 14 15 and 16 had increased air flow resistance with increased length of the stents.

3. Specificity of each filter type, such as solidity or fiber diameter, also determined the air flow resistance. Stents No 12-16 could not be used due to their high solidity.

4. Humidity from respiratory tract and atmosphere which deposited on the filter fiber surface increased the air flow resistance.

5. In highly air-polluted areas, contaminated substances on the filter materials should decrease the filtration efficacy with prolonged usage.

During the experiment, there were no complications or side effects. No foreign body remained in the respiratory tract. The cost of the filter and stent materials were cheap and available. The different airflow resistance from both nasal cavities varied by the nasal cycle. Further experiments to test efficacy and type of filter should be evaluated with the following goals:

1. Special filter material such as electrically charged fiber or mixed fiber should be tried in order to maximize the filtration efficancy for SPM[9,23].

2. The resistance to nasal air flow from the filter material should be minimized. The material at both ends of the stent should be used to prevent movement of the filter inside during respiratory phases[19]. The inside filter should be used with low solidity and packed loosely in the stents[24].

3. The efficacy of the filter should be tried in a field survey situation, especially in congested traffic areas.

4. The deposition of particles on each layer of the filter could be detected by light or electron microscopy before and after exposure to the SPM. The optical particle counter; such as Royco model 225 or PMS model LAS-X PMS Inc. Boulder, Cololado, was used for particle count in the air but it was difficult for particle count in the respiratory tract.

5. CT scan or MRI for estimation of vestibular size in a Thai population was suggested to select the proper shape of filter and stent.

6. SPM composed of different sizes of particles. The aerosol generator; such as TSI Inc, model 345000, St.Paul, Minissota, could create monodispersed or polydispersed aerosol and should be used in the laboratory with a manikin such as Jacobi & Eisfeld (J-E), 1980 or James & Birchall (J-B), 1981.

SUMMARY

Different kinds of intranasal synthetic stents and filters in this pilot study were proposed for personal protection of the SPM in the general population. A silicone stent with one layer of face mask or surgical mask at each end should be the suitable material. Nasal airflow resistance was measured by the anterior standard rhinomanometric method. The cost of the filter and stent was cheap and they are available. Complications or side efffects of the respiratory tract did not occur. The effectiveness of the products should be further evaluated by a field survey in critical air polluted areas.

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การทดลองใส่วัสดุกรองสังเคราะห์ในช่องจมูกเพื่อป้องกันฝุ่น ประเมินด้วยเครื่องตรวจวัดการไหลเวียนอากาศผ่านช่องจมูก

*ครรชิตเทพ ตั้นเผ่าพงษ์, พ.บ.**

การทดลองศึกษาผลของวัสดุกรองและเครื่องมือสำหรับยึดรูเปิดชนิดสารสังเคราะห์ซึ่งใส่ในช่องจมูกเพื่อใช้ป้องกันฝุ่นที่จะเข้าสู่ระบบทางเดินหายใจ การประเมินผลการใช้ผ้าปิดปากและจมูกซึ่งใช้ในห้องผ่าตัด การวัดขนาดช่องจมูกส่วนโพรงหน้าของผู้ใหญ่ในคนไทย ทำการทดสอบวัสดุกรองชนิดต่างๆ ด้วยเครื่องมือตรวจวัดการไหลเวียนของอากาศผ่านช่องจมูก ค่าความต้านทานชนิดมาตรฐานด้านหน้าของช่องจมูกใช้เปรียบเทียบกับอาการแน่นจมูกได้ดี ส่วนประกอบด้านนอกและด้านในของแผ่นผ้าปิดปากและจมูก ซึ่งปิดปลายท่อซิลิโคนทั้งสองด้านเป็นวัสดุในการป้องกันกันฝุ่นซึ่งเหมาะสมที่สุด ราคาถูกและหาได้ง่าย ไม่พบอาการแทรกซ้อนหรืออาการข้างเคียง สำหรับประสิทธิภาพการกรองฝุ่นเพื่อใช้สำหรับประชากรทั่วไป ควรทำการทดสอบในช่วงระยะเวลาที่มีปริมาณฝุ่นสูง

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