A suction catheter comprising an elongated flexible plastic tube having a lumen running interiorly thereof and defining an opening at the distal end. Means are provided at the proximal end for connecting the catheter to a source of vacuum. The distal end of the tube is provided with laterally extending flange means and a plurality of apertures are defined through the tube into the lumen immediately proximal of the flange means for producing a flow of gas over the flange means to provide a gaseous cushion between the flange means and the wall of a body cavity into which the catheter is to be inserted thereby assisting in maintaining a spaced relationship therebetween.
SUCTION CATHETER

This application is a continuation-in-part of application Ser. No. 196,602 filed Nov. 8, 1971 now abandoned.

The instant invention relates to a catheter construction and relates more particularly to a suction catheter for insertion into a body cavity. The catheter of this invention is useful in many body cavities such as the rectum and the stomach. However, since one of the primary uses for suction catheters resides in suctioning of the nasopharyngeal airway and the tracheobronchial tree, the emphasis herein will be directed to this application. Suctioning of the tree is usually accomplished by passing a suction catheter through an endotracheal tube or tracheostomy tube down into the tracheobronchial tree. A great majority of the suction catheterization done in hospitals today is done in the Intensive Pulmonary and Coronary Care Units. Many patients in these units have tracheostomy tubes inserted. Because tracheostomy patients have difficulty in bringing up the foreign matter, i.e., secretion and mucus, from the tree, these patients require suctioning between 30 and 60 times a day. This, of course, is deep suctioning of the tracheobronchial tree.

The trachea is a tubular structure 4 to 5 inches long which consists of 16 to 20 U-shaped cartilages separated by fibrous connective tissue. The trachea branches off into two bronchi, the right mainstem bronchus which is wider and shorter and less abrupt in its divergence from the trachea than the left, and the left mainstem bronchus which is longer but smaller in caliber than the right. It is very difficult to suction the left bronchus because of its sharp divergence from the tracheobronchial path. The cartilage ring of the trachea continues into the bronchial tubes until it reaches approximately 1 mm. thickness in diameter. The innermost lining of the tracheobronchial tree is called the mucus membrane and is composed of areolar and lymphoid tissue and presents a well marked inner membrane supporting a stratified epithelium. The next layer is the sub-mucosa layer and is composed mainly of a mixed layer of blood vessels, nerves and mucous glands.

In 1956 Plum and Dunning, Technics for Minimizing Trauma to the Tracheobronchial Tree after Tracheotomy, New Eng. J. Med. 254:193–200, reported that non-interrupted vacuum during tracheobronchial suctioning might lead to severe mucosal damage. They pointed out that if the suction catheter adhered to the mucosa and was pulled directly away from it, such a technique was tantamount to a crude biopsy. Indeed, they often found blood aspirate which contained mucosal tissue with routine suctioning of the tracheobronchial tree of patients. Further, in a necropsied series of tracheostomized patients who had been repeatedly suctioned, they noted scattered hemorrhages and edema in the right but not the left bronchus. In addition, extensive microscopic damage was found even in those areas lomed.

Yet another object of this invention is the provision of a catheter construction which includes a flange means surrounding the distal end of the catheter and small side holes immediately proximal of the flange means to produce a laminar air cushion over the flange means which promotes centering of the catheter within the airway, the flange means itself also providing a mechanical impediment assisting in preventing the end hole of the catheter from contacting the side wall of the airway. These two factors prevent the damage caused by indrawing of the mucusa into the eye of the catheter. Thus, the catheter of the instant invention minimizes damage to the tracheobronchial mucosa which is caused by presently available suction catheters and aids conduct a prospective bronchofiberscopic study of the tracheobronchial damage associated with prolonged endotracheal intubation. Mucosal hemorrhages and erosions distal to the tip of the endotracheal tube both in the trachea and right bronchi within a few hours after intubation were noted. Since it has long been recognized that straight suction catheters invariably enter the right bronchus, the location of these lesions was consistent with the suction catheter damage observed by Plum and Dunning, supra. Indeed, in one patient in whom the endotracheal tube had been placed within the right bronchus by error, these lesions were only present in the right and not in the left bronchus.

The foregoing damage occurs basically because the suction catheters commercially available at the present time are end hole and side hole catheters. When the suction catheter comes into close contact with the mucosa, the catheter with the vacuum regulating device closed, elevates the mucosa and invaginates it into the end or side holes of the suction catheter. Following cessation of the vacuum, the mucosa invaginated by the suction catheter usually will display two responses. In most instances, the area invaginated becomes immediately hemorrhagic. In some instances the area becomes pale white and within ten to twenty seconds, hemorrhagic. Mucosal hemorrhages are the result of ischemia due to the occlusion of the vascular supply resulting from the invagination of the mucosa into the end or side holes of the suction catheter. These lesions serve as a nest for bacteria. Basically, the suction catheters on the market will allow a little mucus to enter the side or end holes, and when full vacuum is applied, it causes full suction to be applied on the side or end hole that is not partially occluded. This traumatizing effect results in erosion of the epithelial tissue, edema of the mucosa and submucosa layers and can lead to erosion and ulceration of the submucosa which, of course, causes bleeding and is dangerous to the patient. In many instances, the findings are not as noticeable microscopically as microscopically when examined by the pathologist.

It is the primary object of the instant invention to provide a new catheter construction which overcomes to a major extent the foregoing and other such disadvantages.

A further object of this invention is the provision of a catheter which includes means to provide an air cushion surrounding the distal tip to assist in maintaining a spaced relationship the distal tip to assist in maintaining a spaced relationship between the eyes of the catheter and the wall of the airway into which the catheter is inserted.

Yet another object of this invention is the provision of a catheter construction which includes a flange means surrounding the distal end of the catheter and small side holes immediately proximal of the flange means to produce a laminar air cushion over the flange means which promotes centering of the catheter within the airway, the flange means itself also providing a mechanical impediment assisting in preventing the end hole of the catheter from contacting the side wall of the airway. These two factors prevent the damage caused by indrawing of the mucosa into the eye of the catheter.
in minimizing bacterial colonization in patients who require suctioning of the tracheobronchial tree.

Other and further objects of this invention will be obvious to those skilled in the art from the following detailed description which makes reference to the accompanying drawing illustrating a preferred embodiment of the instant inventive concepts.

FIG. 1 is an elevational view, partly broken away for illustrative clarity, of a suction catheter incorporating the instant inventive concepts; and

FIG. 2 is a fragmentary longitudinal cross-sectional view taken along lines 2-2 of FIG. 1 and showing the airflow around the distal tip of such a catheter in a body airway.

In order to test the efficiency and safety of commercially available suction catheters, and compare the same to the catheter of the instant invention, various experiments were designed as follows.

**Animal Experiments** - Forty mongrel dogs were anesthetized with pentobarbital 25 mg per Kg such that spontaneous respiration was preserved. A flexible bronchofiberscope was passed directly into the tracheobronchial tree, the mucosa examined and control 35 mm. still photographs or 16 mm. cine obtained. The following commercially available suction catheters of 14F and 18F diameter were directed into a major or minor bronchus: 1) Bard Parker Reg-U-Vac, 2) Superior Safety Control, 3) Davol Red Rubber, 4) American Hospital Vacutur, 5) Cutler Resoflex, 6) Bard With Airport Adaptor, 7) Rusch, 8) Argyle, 9) USCI, 10) Pharmaseal, and 11) Abbott free part. Each catheter was employed in a minimum of three animals. In 10 dogs, attempts were made to produce lesions during bronchofiberscopic observation by forcing the tip of the catheter against the bronchial mucosa without use of vacuum. The catheters were connected to a Puritan Vacuum Apparatus and different levels of vacuum (40 to 200 mm. Hg.) were briefly and repetitively applied by occluding the proximal vacuum bled hole or vacuum regulator of the catheter as in a clinical situation.

**Model Airway** - To simulate what was seen in the animal experiments, a finer cut was made through a latex glove and mounted on a ring stand to function as a model of an airway. Catheters were passed along the wall of this model and patterns observed when vacuum was applied.

**Efficiency of suction** - This was tested by immersing one or more of the eyes of the catheter into a beaker of water and timing the rate of removal of the fluid.

**Airflow patterns around catheter** - Flow of cigar smoke generated in sidearm flask was observed flowing past the head of the catheter and into the side ports of the catheter. The catheter was housed in a Plexiglas cylinder approximately 2 inches in diameter and 18 inches long. The suction applied to the catheter from a source external to the cylinder was responsible for pulling the smoke from the reservoir into the catheter.

The following results were realized with the commercially available catheters.

**Animal Experiments** - All commercially available catheters tested gave similar results. In no instance did touching the tip of the catheter to the mucosa without application of vacuum produce grossly visible lesions. When vacuum was applied, and the eyes of the catheter came into close proximity with the bronchial mucosa, the mucosa elevated and invaginated into the side hole or end hole or both depending upon the configuration of the catheter tip. Following cessation of vacuum, the area of mucosa invaginated by the suction catheter displayed two responses. In most instances, the area became hemorrhagic immediately but rarely it first became pale white and within 10 to 20 seconds hemorrhagic. Lesions were produced at all levels of vacuum from 40 to 200 mm. Hg, but were more readily induced at the higher settings. At the time the mucosa occluded all eyes of the catheter, the vacuum regulator indicated full vacuum.

In catheters with single holes or with two holes placed parallel to each other, slight damage was often produced when only the side hole came into contact with the mucosa. Greater damage was found when the side hole contacted the mucosa and the end hole was also touching the mucosa or occluded by secretions.

**Model Airway** - When vacuum was applied to end hole catheters, and the catheter was drawn along the wall of the model, immediate collapse of the simulated airway was seen. When a catheter with an end and side hole was used, minimal local indrawing of the latex wall into the side hole was seen. Graded occlusion of the end hole with bone wax produced accentuation of this phenomenon, and complete occlusion of the end hole analogous to occlusion with secretions or contact of the end hole with bronchial mucosa gave the same result as a single end hole catheter. Catheters with parallel side holes and a closed end produced similar collapse of the latex wall.

**Efficiency of suction** - The end hole of the catheter was placed into a beaker of water and vacuum was applied. In both the end hole plus a close by proximal side hole, prompt removal of the water occurred. In catheters in which two side holes were staggered at a distance from the tip, (Saklad Catheter, Davol) no water was taken up through the end hole; only when the side holes were placed in the water, did the catheter function efficiently.

The foregoing results confirm the observations of Plum and Dunning, supra, that the tracheobronchial mucosa may be damaged by suction catheters. Even with brief interrupted suction, as soon as the eye of the suction catheter contacts the mucosa, hemorrhage and erosions of the mucosa are produced. This is because the vascular supply is occluded by the border of the eye of the catheter as the mucosa is invaginated into the eye of the catheter. The frequency of these lesions appears to be directly related to the magnitude and the length of time that the vacuum is applied. Moreover, these lesions cannot be prevented unless such low levels of vacuum for brief time intervals are applied, that there is a complete loss of efficiency for aspiration of secretions. Plum and Dunning found mucosal damage in cats suctioned with standard catheters both with continuous suction and to a lesser extent with optional brief periods of interrupted suction. Thus, it is apparent that the design of present day suction catheters is unacceptable because no provision is made for preventing the eyes from contacting the wall of the airway being suctioned.

Although gross lesions were not observed by bronchofiberscopy after stroking the mucosa with the tip of the suction catheter this does not exclude damage
which might be present microscopically. Indeed, Hilding, Time-lapse Relation to Changes in the Respiratory Epithelium After Minimal Trauma. Acta Otolaryng. 57:352-366, 1964, has shown that light stroking of extirpated trachea with a cotton swab causes progressive loosening from one another of the columnar cells and cleavage from the underlying cells with complete exfoliation of the columnar layer over a 1 to 24 hour period.

 Destruction of ciliated epithelium by the suction catheter suppresses mucous clearance. This predisposes the tracheobronchial tree to obstructive crusting. Further, the destruction of the mucous clearance mechanism might also explain the high incidence of bacterial colonization in intubated and tracheostomized patients who are usually subjected to suctioning.

The foregoing investigations suggested that protection of the mucosa from suction catheter damage was only possible if the holes of the catheter could be prevented from contacting the mucosa. The prototype of the instant invention was a rubber “O” ring cemented to the cut-off end of a straight plastic catheter. The basic concept behind this construction was that the O-ring would physically prevent a single end hole from contacting the sides of the airway. However, this prototype was unsuccessful because contact of the end hole with a bronchial bifurcation or flush to the mucosa of a small airway gave the same damage as the end hole catheters.

The tip was then modified according to the preferred embodiments of the instant inventive concepts. In order to better understand the same, reference is made to the drawings wherein a catheter construction according to this invention is designated generally by the reference numeral 10. The catheter 10 includes an elongated tube 12 having a distal end 14 and a proximal end 16 with a lumen 18 running interiorly thereof and defining an opening means 20 at the distal end.

The tube 12 can be made of any non-toxic material, preferably a relatively flexible plastic material such as natural or synthetic rubber, polypropylene, polyethylene, polyvinyl chloride, nylon or the like. The particular material is not critical and those skilled in this art can readily select suitable materials to provide adequate flexibility and resilience for the intended use.

Any conventional means may be provided at the proximal end for connecting the catheter to a source of pressure lower than that existing at the distal end of the tube in use, usually a vacuum. In the embodiment of FIG. 1 a bulbous portion is shown at the proximal end for connection of the catheter 10 to the tubing from a source (not shown) of vacuum or the like. An eye 22 may be provided as a relief hole so that the user can make and break the negative pressure through the lumen 18 in a well known manner.

The tube 12 is provided with a laterally extending continuous flange means 24 contiguous to and surrounding the distal end. In the manufacture of the catheter, this bead or flange means can be formed in a number of ways. A conventional catheter made from thermoplastic material can be heated to provide a large ring at the free end thereof, or a preformed ring can be thermoplastically sealed or adhesively attached to the distal end of the tube. Preferably, however, the flange means is integrally formed at the distal end of the tube and has an arcuate peripheral surface as shown in the drawing.

Immediately proximal of the flange means 24, aperture means 26 extend through the tube 12 into the lumen 18. Preferably, the aperture means comprises a plurality of equally circumferentially spaced apertures, four such apertures being shown in the illustrative embodiment in the drawings.

The aperture means, in combination with the flange means function to produce a laminar flow of gas from the airway, schematically shown at 28 in FIG. 2, over the flange means to produce a gaseous cushion between the flange means 24 and the wall of the body cavity or airway 28 into which the catheter 10 is to be inserted, thereby assisting in maintaining a spaced relationship therebetween and helping to center the distal tip of the catheter in the airway. The flow of gas into the opening means 20, and the laminar flow over the flange means 24 into the aperture means 26 is schematically shown in FIG. 1 by the arrows 30.

Selection of the optimum dimensions for a catheter construction which satisfies the instant inventive concepts may be accomplished by those skilled in the art having the foregoing teachings available to them. The size of the proximal side holes or apertures 26 can be readily determined for a given size catheter by forming the holes just large enough to provide a slight sensation of vacuum when the end hole or opening means 20 is touched to the cheek of the face during the application of 160 mm. Hg of vacuum at the proximal end of the tube. This subjective test can be readily reproduced, and basically comprises formation of the aperture means in such a manner as to produce a nominal vacuum at the opening means during the application of such a vacuum to the catheter.

As exemplary of optimum dimensions, for a 14F catheter wherein the tube has an outside diameter of 0.181 ± 0.004 inches and a wall thickness of 0.028 inches, the flange means has an outside diameter of 0.265 ± 0.010 inches and a radius of 0.035 inches and the aperture means comprise four equally circumferentially spaced apertures having a diameter of 0.059 ± 0.002 inches, with the distal edge of each of the apertures which is proximal to the flange means being no more than 0.015 inches therefrom. Actually, it is desirable to have the aperture means as close to the proximal edge of the flange means as possible, zero spacing being optimum. However, from a practical standpoint, since these apertures are punched with a tubular die, obviously having a wall thickness, the ideal positioning is limited by the thickness of the die wall.

For an 18F suction catheter wherein the tube has an outside diameter of 0.221 ± 0.004 inches and a wall thickness of 0.032 inches, the flange means has an outside diameter of 0.31 ± 0.010 inches and a radius of 0.038 inches, with the aperture means preferably comprising four equally circumferentially spaced apertures having a diameter of 0.063 ± 0.002 inches, the distal edge of each of the apertures again being placed as closely as possible to the proximal edge of the flange means in order to produce the desired air flow as illustrated in FIG. 2.

Again, the foregoing dimensions are given as optimum illustrations for 14F and 18F suction catheters. Those skilled in the art can select proper dimensional relationships to produce the desired functional characteristics from the teachings herein.
Subjection of a catheter according to the instant inventive concepts to the foregoing experiments produced the following results.

**Animal experiments** - In the trachea, main bronchi, and lobar bronchi of animals, the suction catheter of this invention tended to remain in the center of the airway such that no damage could be detected by bronchosfiberoscopic observation. However, mucus left the walls of the airway to be aspirated by the catheter. When the catheter was impacted into a segmental or subsegmental bronchus, vacuum from the catheter caused the segment to be evacuated by the catheter and the lumen collapsed around the catheter. However, even under these conditions, minimal or no erosions were visible by bronchosfiberoscopy.

**Model Airway** - The suction catheter hereof was tested in the latex finger model of the airway. There was little or no collapse of the latex wall toward one of the proximal side holes or apertures as the catheter was drawn back and forth along the wall. Thus, the design of this catheter prevented the wall from being suctioned into a side hole thereof. The 14F catheter performed better under this test because of a more favorable relation of the thickness of the flange means to the size of the apertures than the 18F model. The thickness of the flange means in the 18F catheter was limited by the desire not to increase the overall diameter to a size that would be unacceptable to passage through nasophrangeal and edotracheal tubes. Graded occlusion of the end hole or opening means by bone wax did not produce significant collapse of the latex wall of the model.

**Efficiency of suction** - Immersion of the end hole of the catheter of this invention into the surface of the water such that the side apertures were exposed to air produced prompt removal of water as soon as vacuum was applied. The efficiency of suction of the fluid under this condition was about 30% slower than when the entire catheter tip was immersed in the water.

**Air flow around catheter** - The air flow pattern around the catheter was revealed by smoke which flowed around the tip when vacuum was applied. Air flowed through the end hole or opening means and around the flange means to produce an air cushion over the surface of the flange means in order to enter the proximal side apertures as schematically illustrated in FIG. 2.

Thus, it will now be seen that there is herein provided an improved suction catheter which satisfies all of the objectives of the instant invention, as set forth above, including many advantages of great practical utility and commercial importance. It shall be understood that the foregoing illustrative embodiments are intended as exemplary and that various modifications and changes may be made without departing from the instant inventive concepts.

I claim:

1. A suction catheter of a size suitable for insertion into a body cavity containing a gas such as the nose, mouth or laryngotracheobronchial tree, comprising an elongated tube formed of a flexible material having a lumen running interiorly thereof, said tube having a distal end with an opening for placing said lumen in communication with the interior of the body cavity and a proximal end adapted to place said lumen in communication with a source of pressure lower than that existing at the distal end of said tube, regulation means for controlling, from said proximal end, the suction applied at said distal end, aperture means near said distal end extending through said tube into said lumen, and flange means extending laterally from said tube adjacent said aperture means and between said aperture means and said opening to maintain said aperture means spaced from the walls of said body cavity thereby aiding in preventing occlusion of said aperture means upon application of suction to said catheter.

2. A suction catheter according to claim 1 wherein the area of said aperture means is sufficient to permit only a nominal vacuum at said opening upon application of suction to said catheter.

3. A suction catheter according to claim 1 wherein said flange means is a continuous ring extending about the periphery of said tube contiguous to said distal end, and said aperture means is immediately proximal of said ring, whereby flow of gas over said ring provides a gaseous cushion between said ring and the wall of the body cavity into which the catheter is inserted to assist in maintaining a spaced relationship therebetween.

4. A suction catheter according to claim 3 wherein the edge of said opening and flange means are smoothly rounded.

5. A suction catheter according to claim 1 wherein said aperture means comprises a plurality of equally circumferentially spaced apertures.

6. A suction catheter according to claim 5 wherein the diameter of said aperture means is sufficient to produce a nominal vacuum at said opening means when a vacuum of 160 mm. Hg is applied to the proximal end of said tube.

7. A suction catheter according to claim 6 wherein for a tube having an outside diameter of 0.181 ± 0.004 inches and a wall thickness of 0.028 inches, said flange means has an outside diameter of 0.265 ± 0.010 inches and a radius of 0.035 inches, said aperture means comprises four equally circumferentially spaced apertures having a diameter of 0.059 ± 0.002 inches, the distal edge of each of which is proximal of said flange means no more than 0.015 inches.

8. A suction catheter according to claim 6 wherein for a tube having an outside diameter of 0.221 ± 0.004 inches and a wall thickness of 0.032 inches, said flange means has an outside diameter of 0.31 ± 0.010 inches and a radius of 0.035 inches, said aperture means comprises four equally circumferentially spaced apertures having a diameter of 0.063 ± 0.002 inches, the distal edge of each of which is proximal of said flange means no more than 0.015 inches.

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