Feasibility Study

Abdominal Fat Suspension Device for Maintaining Normal Cardiorespiratory Function

in Patients Undergoing Conscious Sedation during Surgery: A Feasibility Study

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Obese patients undergoing conscious-sedation surgery have increased perioperative morbidity because their excess abdominal tissue limits diaphragmatic excursion. We describe a simple device that might help attenuate this risk. We created a noninvasive suction device for abdominal suspension. By lifting the burden of excess weight, this device should decrease respiratory effort. To test the feasibility of excess weight removal in relieving cardiac stress, we tested 22 supine, healthy, normal-weight subjects by measuring their heart rates with and without a 13-kg tissue model on their abdomen to simulate excess weight. There was no significant difference in blood oxygen saturation before and after weight removal (P=0.318). However, the decrease in heart rate was significant (P <0.0001; paired 2-sample, one-tailed t test), which implies decreased respiratory effort. This result suggests the possibility that abdominal mass suspension in obese patients is associated with decreased respiratory effort. ***(Tex Heart Inst J 2014;41(4):368-72)***

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Obesity has reached epidemic proportions in the United States. In 2010, more than 70% of the American adult population was considered either overweight or obese.[1] Obesity causes numerous health problems and can adversely affect the outcome of surgical procedures. The risk is particularly prominent during minor surgery performed on patients who are under conscious sedation. Because conscious sedation relaxes the muscles and lowers the stress response, it generally results in decreased exerted respiratory effort.[2] In obese patients lying supine during these operations, the excess abdominal weight restricts the downward movement of the diaphragm and the chest wall, further hindering respiration.[3] In approximately one third of minor operations performed on obese patients who are under conscious sedation, the excess weight poses such a barrier to respiration that sudden hypoxemic episodes occur as their blood-oxygen levels plummet. In such a situation, the procedure must be interrupted to stabilize the patient's condition; this can result in trauma to the patient, increased procedural costs, and postoperative complications.

Because no method is currently available to prevent this problem, we created a noninvasive suction device for suspending the abdomen intraoperatively, thereby relieving the weight of the abdominal fat. We then demonstrated—in healthy, nonobese volunteers—the feasibility of relieving excess abdominal weight to mitigate the respiratory burden.

Materials and Methods

The ultimate objective of our respiratory-aid (R-Aid) device is to aid respiration by physically lifting and suspending the excess fat load to alleviate compression on the obese patient's diaphragm and lungs. This is achieved by means of suction cups that noninvasively interface with the patient's abdomen.

The R-Aid (Fig. 1) consists of 2 main parts: the suction interface itself and the support frame to which it is anchored. Four cups with soft rubber rims—designed to minimize bruising—are attached directly to the abdominal skin. A suction generator is attached to the cups via tubing and other connecting components. When the gen-

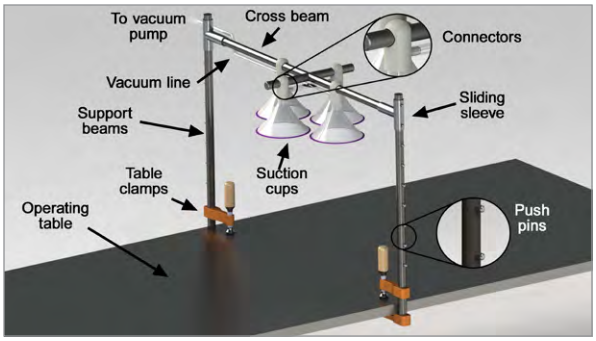

Fig. 1 *Diagram shows the respiratory-aid device in position on the operating table.*

erator is activated, it produces a suction force, oriented perpendicular to the abdomen, that can support 13 kg of abdominal weight with an airtight seal.

The support frame, anchored to the operating table, is positioned around the patient's abdominal area, so that the horizontal beam (holding the cups) is suspended over the abdomen. The cups are applied to the center of the abdomen, where the skin surface tends to be flat despite curvature. This arrangement, along with the height-adjustable frame, enables the device to be used on abdomens of various sizes.

Suction Component

The R-Aid uses a suction machine produced by Drive Medical Design and Manufacturing (Port Washington, NY). The machine is compact (23 × 25 × 20 cm) and easily portable. The amount of suction pressure is controlled by a valve. Silicone tubing is attached to the spout of the suction machine and then to the outlet of the closest connector; the 4 cups are connected by cross-shaped silicone tubing (Fig. 1).

The cups themselves (diameter, 10 cm) are breast-pump flanges (Lansinoh Laboratories, Inc.; Alexandria, Va). The final design uses 4 cups, which collectively can support 13 kg with less than 5 inHg of suction pressure. This amount of suction pressure is considered low enough to avoid long-term bruising.[4] Although applying additional cups would reduce the suction pressure required to lift the same amount of weight, fitting more than 4 cups onto the abdomen would be difficult.

Frame Component

The R-Aid's pushpin H-shaped frame consists of 2 vertical support rods that are 58 cm in height and 2 cm in diameter and of an attached horizontal crossbar 91 cm in length. Its 3 components can be assembled and disassembled in less than 10 minutes. On the end that fastens to the operating table, each support rod has a clamp. The horizontal beam accommodates patients of various girths by connecting to the support rods via height-adjustable sleeves. These sleeves, by incorporating pushpins in 2.50-cm increments along the vertical rods, can slide along the legs and lock in place (Fig. 1). The frame itself can support more than the target weight of 13 kg for an extended period.

Feasibility Study

Because the R-Aid might not yet be safe enough to be used for obese patients, we recruited 22 healthy, nonobese volunteers to test the effects of excess-weight removal on respiration as part of a feasibility study. This study (Protocol 12-145E: Developing an abdominal suspension device for obese patients during surgery) was approved by Rice University's Institutional Review Board (IRB) through an expedited review that was in accordance with Title 45, Part 46, Section 46.110 of the Code of Federal Regulations (Category 4). Each subject signed an IRB-approved informed-consent form.

The subjects ranged in age from 18 to 22 years. Before this, testing of the device on a single healthy volunteer over a period of 2 hours had produced no suction-induced hemorrhage or bruising, despite the use of aspirin.

Each subject lay supine on an operating-type table, and his or her oxygen saturation level and heart rate were measured with a pulse oximeter. In addition, the respiration rate was measured by counting the number of breaths per minute. First, measurements were recorded at 10-s intervals for 1 min to ensure initial stable respiration and to set a baseline for the measurements. A 13-kg tissue model was then placed on the subject's abdomen, to simulate the burden that excess abdominal weight places on breathing in obese patients. The oxygen saturation level, heart rate, and respiration rate were then measured at 10-s intervals for 5 more min. The tissue model was then removed, and the same 3 measurements were obtained for another 2 min. Removal of the tissue model by lifting it off the subject was analogous to the act of abdominal suspension in obese patients. After the test, each subject was asked to rate his or her level of comfort before and after weight removal on a scale from 1 to 5, with 5 being "most comfortable." Although healthy, nonobese human subjects were recruited for this feasibility study, we intend to use obese subjects for future testing.

Results

The respiration rates and oxygen saturation levels registered no significant changes during the test (P=0.124 and P=0.318, respectively). However, the average normalized heart rate increased after the weight was applied at 1 min and decreased after the weight was removed at 6 min (Fig. 2).

To verify the significance of the heart-rate changes, we conducted a paired 2-sample, one-tailed t test, analyzing the differences between the subject's heart rate before weight application and during weight application, and between the subject's heart rate during weight

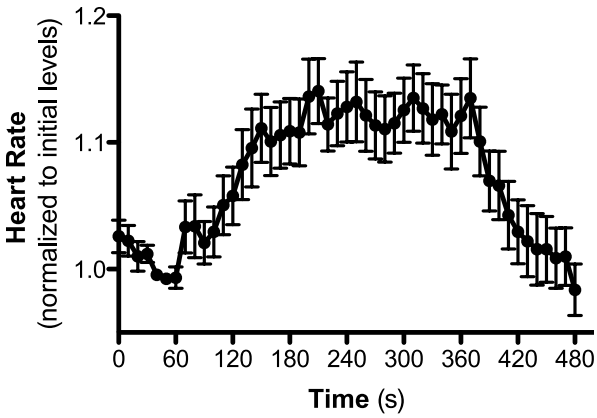

Fig. 2 *Graph shows that the heart rate was normalized to individual subject's baseline heart rates, which were calculated by averaging the subject's heart rates over t=30 to t=60 s, and plotted over time. Data points indicate normalized means at each time point, and error bars indicate SEM. The weight was applied at t=60 s (1 min) and removed at t=360 s (6 min).*

t = time

application and after weight removal. We chose to use a one-tailed test because only heart-rate increases between values before and during weight application, and heart-rate decreases between values during weight application and after weight removal would show the efficacy of the excess-weight removal. The average increase in heart rate of 8.24 beats/min due to initial weight application was significant (P <0.0001). The decrease in heart rate of 9.8 beats/min due to weight removal was also significant (P <0.0001) (Table I). Figure 2 plots a sample subject's heart rate.

No significant difference was observed in respiratory rate due to weight application (P=0.124) and removal (P=0.208) (Table II). Nor was any significant difference seen in oxygen saturation levels due to weight application (P=0.318) and removal (P=0.712) (Table III). In addition, all patients reported that they felt more comfortable after weight removal: the average difference between comfort scores before and after removal was 2.6 on a scale of 1 to 5 (P <0.01).

TABLE I. Average Heart Rates before Weight Application, during Weight Application, and after Weight Removal

Sample	Average Heart Rates (beats/min)		
	Before	During	After
1	73.3	82.7	66
2	59.8	65.9	53
3	58	58.3	57
4	71	85.5	64
5	95.8	109.9	77
6	86.8	92.6	85
7	60.8	65.4	59
8	86	94.3	88
9	55.3	65.8	53
10	64.5	71.2	58
11	67.3	76	68
12	88.3	95.2	85
13	58	78.3	67
14	75.5	73.1	72
15	60.5	61.4	64
16	70.5	72.6	73
17	57	68.6	61
18	52.5	77.6	64
19	77.8	83.8	70
20	69.5	74.5	69
21	73	77.3	71
22	75.5	87.6	78

Discussion

In obese patients, suspension of abdominal tissue is known to effectively ease respiration. In 1981, Wyner and colleagues[5] used 2 large Rush rods (hooked rods often used in orthopedic procedures) to pierce the abdominal wall of a 340-kg woman. These rods functioned as an anchor for a hydraulic lift that was used to elevate the abdominal fat. Mechanical lifting of the abdominal wall greatly improved arterial oxygenation and relieved the lungs of excess compression.

We have described a simple mechanism for suspending abdominal weight during procedures that use conscious sedation. We demonstrated the feasibility of removing the burden of excess weight by testing the concept in healthy, nonobese volunteers. A change in heart rate was indeed observed in most of the subjects; however, blood oxygen saturation levels remained constant. In addition, a significant change in respiration rate occurred, possibly because multiple regulatory mechanisms serve to maintain respiratory homeostasis in healthy, conscious human beings. In our healthy subjects, the heart and respiration rates increased when weight was placed on the abdominal region, and these values remained elevated until the weight was removed. This finding implied that the added weight was associated with increased respiratory effort—either to maintain normal blood oxygen levels, to respond to discomfort, or both—and with increased discomfort, in such a manner that elevated effort was manifested by increased heart rate.

Whereas healthy, nonobese subjects can easily increase their heart rates and respiratory efforts, obese patients

TABLE II. Average Respiratory Rates before Weight Application, during Weight Application, and after Weight Removal

Sample	Average Respiratory Rates (breaths/min)		
	Before	During	After
1	23	26	25
2	13	10.5	12.5
3	19	21	24
4	29	26	26
5	23	32.5	21.5
6	16	18	14.5
7	17	28	21
8	18	13	15.5
9	18	27	14.5
10	15	17	18
11	14	9	8
12	15	16.5	16
13	18	17	17.5
14	11	9.5	10.5
15	13	13.5	13.5
16	12	14.5	12.5
17	15	16.5	16.5
18	12	15	14.5
19	7	7.5	7
20	14	15	15
21	12	14.5	12
22	12	12	12

TABLE III. Average Blood Oxygen Saturation Values before Weight Application, during Weight Application, and after Weight Removal

Sample	Average Oxygen Saturation (%)		
	Before	During	After
1	98	98.5	98
2	97	97	97
3	99	98	98
4	97.8	96.2	97
5	96	97	95
6	98	98.8	98
7	98	97	96
8	95.8	93.8	95
9	99	98.4	99
10	98.8	98	98
11	97.3	97.7	97
12	98.3	98.4	99
13	99.3	99.7	97
14	97	96.7	98
15	98.8	98.3	99
16	98.3	98	97
17	99	96.5	98
18	98	98	98
19	98	98	98
20	98.5	98	98
21	99	98	98
22	98.8	98.2	98

with existing heart or respiratory problems might have trouble exerting the extra effort needed to increase these values. Moreover, the application of conscious sedation during surgery can further hinder the drive to achieve these compensatory mechanisms. The current feasibility study shows that excess abdominal weight can lead to increased respiratory effort and discomfort even in healthy volunteers and that displacement of that weight will probably mitigate the changes in respiration and heart rates. Indeed, because the suction device, by design, is able to displace a substantial amount of excess abdominal weight, we believe that it should promote normal respiration in obese patients who are undergoing minor surgery with conscious sedation.

Limitations

The results of the current study cannot necessarily be extended to obese individuals. The ideal study patients would be obese individuals. However, because this was a proof-of-concept study, we elected to perform the initial data-gathering by using healthy volunteers. Although the conclusion cannot be generalized in application to overweight individuals, we believe the preliminary results show potential feasibility that might later be studied in obese individuals.

Summary

To prevent obesity-related hypoxemic episodes during minor surgery involving conscious sedation, we have developed the R-Aid device, which uses suction to grip and suspend excess abdominal weight, thereby relieving the burden of that weight on the supine patient's respiratory system. The current R-Aid prototype is capable of lifting 13 kg of weight with minimal damage to human subjects. Bruising is a possible side effect, but any discomfort resulting from use of the device will probably

be much less than the discomfort arising from surgery and postoperative recovery. Proof-of-concept testing in healthy, nonobese volunteers showed that the removal of excess abdominal weight decreased the respiratory effort needed to maintain normal blood oxygen levels and consequently relieved the respiratory burden and discomfort.

Our next step will be to test this device on obese, healthy volunteers by recording the same values as in the experiment described here. Upon the successful completion of that study, we will then test the R-Aid device in the operating room on consciously sedated obese patients, to ensure smooth integration with the surgical environment and accurate performance in the clinical setting.

Conclusion. We predict that further development of this project will result in a device that will improve patient outcomes in obesity-related minor surgeries requiring conscious sedation.

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