Mechanical Ventilator Malfunctions: A Descriptive and Comparative Study of 6 Common Ventilator Brands

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BACKGROUND: Estimates suggest that there are as many as 50,000 mechanical ventilators in use in the United States alone. Yet, the medical literature is nearly devoid of information describing or discussing the issue of ventilator malfunctions. The purpose of this study was to investigate how and what types of mechanical ventilator malfunctions occur, whether there are significant differences in the malfunction rates of 6 common ventilator brands, and whether there are differences in ventilator purchase prices and long-term maintenance costs. MATERIALS AND METHODS: A retrospective review was done using hospital repair, maintenance, and billing records between July 1, 1991, and January 3, 1999. A total of 75 individual ventilators of 6 different brands were followed: 13 Bear Medical Cub ventilators (CUB), 11 Mallinckrodt Nellcor Puritan Bennett Infant Star ventilators (STAR), 8 Bird VIP ventilators (VIP), 11 Bird 6400ST ventilators (6400ST), 16 Bird 8400STi ventilators (8400 STi), and 16 Mallinckrodt Nellcor Puritan Bennett 7200ae ventilators (7200ae). The dependent variable was the operating time before malfunction, which was determined by the difference between hours logged on each ventilator's hour meter at the time of malfunction and that recorded at the outset of the study. Thereafter (when applicable), the time before malfunction was the difference in hours at successive malfunctions. Malfunctions were of 2 types: mechanical failures and operator errors. Price and maintenance information was obtained by personal communication. RESULTS: In 2,201,771 hours of ventilator operation, only 282 malfunctions were reported; of these, 176 were classified as mechanical failures, 106 as operator errors. There were no documented instances of long-term patient harm secondary to any type of ventilator malfunction. There were significant differences between some of the ventilator brands in the frequency of mechanical failures, operator errors, and the number of overall malfunctions experienced. There were also small differences in long-term maintenance costs, while purchase prices showed a considerably larger range. Curiously, modern ventilators may not suffer an increasing rate of malfunction as they age. Finally, if these 75 ventilators are representative of ventilators in general, modern ventilators may be as prone to human errors as were their predecessors. CONCLUSIONS: The data suggest that modern mechanical ventilators are rugged and safe, but not necessarily easier to use. Comparing differences in malfunction rates, maintenance costs, and purchase price offers hospitals a powerful tool for reducing the costs associated with mechanical ventilation. Furthermore, if the trend toward fewer malfunctions as a ventilator ages is validated, hospitals might wish to consider maintaining ventilators longer before replacing them. [Respir Care 1999;44(10):1183–1192] *Key words: mechanical ventilator malfunction, mechanical failure, maintenance cost, repair cost, operator error, survival analysis.*

Background

Several centuries ago, both Vesalius (1555) and Hooke (1667) demonstrated principles fundamental to the concept of mechanical ventilation.[1] Unfortunately, these pioneering efforts went virtually unrecognized, and mechanical ventilators did not gain widespread acceptance for nearly 200 years. Physicians in the United States were

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particularly recalcitrant; many still bitterly disputed the value of mechanical ventilation as late as the 1950s.[2] Eventually, it took a catastrophe (the polio epidemic of the mid-1950s) to irrefutably prove the value of mechanical ventilation. Since then, the growth in ventilator utilization has been nothing short of astonishing. Recent estimates suggest that today one third to one half of all intensive care unit (ICU) patients receive ventilatory support at some point during their hospital stay.[3] In the United States alone, 50,000 or more mechanical ventilators are currently in use, and, as many as 1,500,000 patients receive some form of ventilatory support outside of operating rooms and recovery rooms each year.[4,5]

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Considering the number of patients receiving ventilatory support, and the mechanical complexity of the ventilators now in use, a large number of ventilator malfunctions seem inevitable. Yet, the medical literature is nearly devoid of information describing or discussing the subject. Possibly, clinicians fear embarrassment or litigation[6] following publication of a report of complications secondary to a ventilator malfunction. Or clinicians might believe that because ventilators are so mechanically dissimilar, a problem associated with one brand would not be relevant to another.[6] Regardless of the cause, failure to report a ventilator malfunction delays expeditious solutions and increases the risk of recurrence of the same malfunction elsewhere. One example would be that, prior to the early 1970s, the temperature of gases inspired during mechanical ventilation often went unmonitored, until a report detailed a case of hemorrhagic, bronchospastic tracheobronchitis secondary to an overheated ventilator "hot pot."[7] More recently, safer pressure-relief valve designs and increased surveillance have followed publication of a fatal incident of neonatal pulmonary barotrauma involving such a valve.[8]

Along with a dearth of data describing ventilator malfunctions, virtually no independent scientific data exist comparing mechanical failure rates or the expected reliability of common ventilator brands. This fact is even more surprising because a single ventilator repair can cost $1,000 or more,[9,10] and most hospital administrators are currently preoccupied with cost-containment.

This study describes the number and types of malfunctions experienced by 6 common brands of mechanical ventilator used at 2 different institutions over a period of up to 90 months. The main objectives were to describe and characterize how and what types of mechanical ventilator malfunctions occur, whether there are differences in the rates of malfunction experienced by different brands of ventilators, and to compare how the long-term cost of owning one of the 6 different ventilator brands compares to the original purchase price.

Materials and Methods

The study consisted of a retrospective review and analysis of hospital billing records, and repair and maintenance records for 6 brands of mechanical ventilators at 2 institutions. A total of 75 ventilators were studied, including 13 Bear Cub Infant ventilators (CUB), 11 Mallinckrodt Nellcor Puritan Bennett Infant Star ventilators (STAR), 8 Bird VIP ventilators (VIP), 11 Bird 6400ST ventilators (6400ST), 16 Bird 8400STi (8400STi) ventilators, and 16 Mallinckrodt Nellcor Puritan Bennett 7200ae ventilators (7200ae).* Each ventilator was used for some portion of or throughout the period beginning July 1, 1991, and ending January 3, 1999. Ventilators of the studied brands, purchased during the course of the study, were enrolled in the study on the date they were placed into use. Once enrolled, each ventilator was either ready for use, or in use throughout the remainder of the study (except for time out for troubleshooting, repairs, or calibration). Each ventilator's age was determined by considering the month and year the ventilator was first available for use as its "birthday."

Institutional repair and maintenance records were obtained for each of the studied ventilators and used to determine the date each ventilator was first placed into service, the date each reported malfunction was noted, the total operating hours logged on the hour meter of each instrument when placed into use, and the hours logged on the day each malfunction was reported. These records also documented the nature and extent of patient injury (if any), and any resulting remedial actions.

Because during the course of the study most ventilators experienced several documented problems, the dependent variable of interest (malfunction) was recorded as a function of the number of hours a ventilator operated without incident between documented malfunctions.

While reviewing the repair and maintenance records, it became apparent that virtually all ventilator malfunctions involved either a mechanical failure or breakdown (including calibration errors) or some sort of operator (human) error. To determine whether a particular ventilator brand was more prone to either of these types of problems, each reported malfunction was categorized. A malfunction was considered a mechanical failure (failure) when the reported problem rendered the ventilator inoperable or unsafe to use until repaired or recalibrated; a malfunction was considered an operator error when, after thorough testing, the ventilator required no repairs or recalibration. For each

*Suppliers of commercial products are identified in the Product Sources section at the end of the text.

studied ventilator, the uneventful operating time (in hours) between (or before) each malfunction was determined from the difference in total operating hours at successive reported malfunctions (or from the hours logged at the start of the study). Operating time was first determined between each successive malfunction of any type, and then between successive malfunctions of the same type (ie, between successive failures and/or successive operator errors).

Manufacturers provided the retail cost of a fully equipped version of each studied brand of ventilator (except the CUB); they also provided the recommended preventive maintenance costs (all in 1999 dollars). The CUB is an exception because it is no longer commercially available; its reported retail cost reflects that in effect when it was removed from the market in 1996. Many CUBs remain in use today, so the preventive maintenance figures reflect those currently available.

Hospital billing records were used to determine the number of patients charged for a day of mechanical ventilation each month. This figure provides a reasonable estimate of ventilator use. It is an estimate because there were a few ventilators used that were not included in the study, and a patient is charged for an entire day of mechanical ventilation regardless of how many hours of that day they require use of the ventilator. Statistically speaking, the records revealed that for each "day" of mechanical ventilation billed, a ventilator operated, on average, between 21 and 22 hours. By combining monthly billing data with monthly malfunctions (failures and operator errors) and ventilator average age data, it was possible to visualize trends in ventilator utilization, average age of the ventilator fleet, rate of occurrence of malfunctions with respect to time, and the interrelationship between these factors over the entire course of the study period.

Statistical Analysis

In this study, the 3 outcome variables all involved the time (in hours) until a terminal event (a malfunction, failure, or operator error). Often, such variables are referred to as survival times because they give the time an individual survived before the terminal event. Survival data (see Appendix 1) present an important analytical problem—how to deal with incomplete or censored observations. Censored observations arise because some individuals may drop out before the study ends or survive until the study ends, so their survival time is indeterminate. Ordinary statistical techniques do not allow for censored observations, but omitting these data could seriously bias a study. For instance, imagine omitting only the study patients that actually survived cancer during trials of a new anti-cancer drug. To address this problem, a separate branch of statistics, known as survival analysis, evolved.

Data for the relative rates of malfunction, failure, and operator error were determined as means with standard deviations; the medians are also provided whenever possible. In some cases, data are presented as 12-month moving averages. Best-fit trend lines were determined using the technique of least squares. The 6 ventilator brands were compared using the survival analysis for multiple groups test; α was set at 0.05 for statistical significance, and post-hoc multiple comparisons were analyzed using the Cox-Mantel test.

For robustness, the multiple groups survival test depends on two important assumptions: (1) a fairly large sample size (at least 25–30 observations), and (2) that each observation is independent.[11] Because the 2 hospitals own a limited number of each studied ventilator brand, and malfunctions occur rather infrequently, gathering sufficient data in a reasonable interval presented an obstacle. However, the number of observations could be increased and data collection expedited if successive malfunctions (occurring with each studied ventilator) were considered as additional observations. This strategy, while practical, must not violate the independence assumption. For repeated operator errors, independence is assured; that is, one clinician's failure to properly use or understand a ventilator is unlikely to influence whether another clinician makes an operator error. Repeated failures are different; as a component within a ventilator fails, it could damage or weaken nearby components, reducing subsequent survival times. Despite this possibility, this premise was rejected and successive ventilator failures were considered independent observations, for two reasons. First, no credible scientific evidence has been published supporting or repudiating the premise; clinicians and hospital administrators assume a repaired ventilator is as safe and reliable as a new, never-before-repaired one. If it were otherwise, ventilators might be disposable items, legally speaking. Second, ventilator manufacturers mandate that field service engineers replace the entire failed subsystem—not just the failed component.

All descriptive statistics and hypothesis testing were performed using Statistica for Windows, release 5.1.

Results

During the 90-month study period, the 75 mechanical ventilators operated for a combined total of 2,201,771 hours (Table 1). During this time, clinicians reported a total of 282 malfunctions (not including censored observations). Table 1 shows a breakdown of ventilator utilization during the study and the types of malfunctions encountered, by ventilator type. None of the reported malfunctions resulted in documented patient injury. One hundred seventy-six (62.4%) of the malfunctions eventually required repair work

Table 1. Ventilator Utilization and Malfunctions by Ventilator Brand*

	CUB (n = 13)	STAR (n = 11)	VIP (n = 8)	6400ST (n = 11)	8400STi (n = 16)	7200ae (n = 16)	Totals (n = 75)
Malfunctions	36 (12)	45 (10)	34 (8)	66 (8)	26 (16)	75 (16)	282
Repairs	14 (12)	39 (10)	17 (8)	42 (8)	19 (16)	45 (16)	176
Operator errors	22 (13)	6 (11)	17 (8)	24 (11)	7 (16)	30 (16)	106
Use during study (h)	344,683	339,465	174,157	295,813	391,993	655,660	2,201,771
Use/year/ventilator (h)	3,632	4,784	3,915	3,426	4,698	6,535	4,647

*Number of censored observations are in parentheses. CUB = Bear Cub Infant ventilator; STAR = Mallinckrodt Nellcor Puritan Bennett Infant Star ventilator; VIP = Bird VIP ventilator; 6400ST = Bird 6400ST ventilator; 8400STi = Bird 8400STi ventilator; 7200ae = Mallinckrodt Nellcor Puritan Bennett 7200ae ventilator.

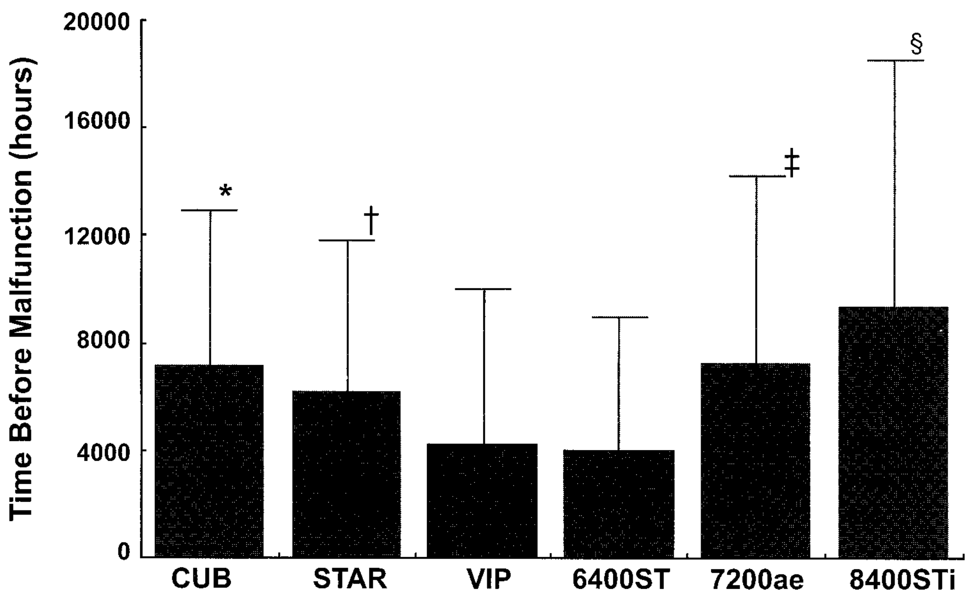

Fig. 1. Hours of ventilator operation before experiencing some sort of malfunction (time before malfunction) for each of the 6 ventilator brands studied. Data are mean ± SD. CUB = Bear Cub Infant ventilator. STAR = Mallinckrodt Nellcor Puritan Bennett Infant Star ventilator. VIP = Bird VIP ventilator. 6400ST = Bird 6400ST ventilator. 7200ae = Mallinckrodt Nellcor Puritan Bennett 7200ae ventilator. 8400STi = Bird 8400STi ventilator. * $p < 0.05$ compared to VIP, and 6400ST. † $p < 0.05$ compared to the 6400ST. ‡ $p < 0.05$ compared to VIP, and 6400ST. § $p < 0.05$ compared to STAR, VIP, 6400ST, and 7200ae.

(or calibration) and were classified as mechanical failures. The remaining 106 (37.6%) malfunctions were classified, by default, as operator errors.

At the end of the study period, the 75 ventilators ranged in age from 1.67 to 15.75 years (mean 8.57 years). Ventilators in this study averaged a malfunction once every 6,265 (3,689 median) hours of ventilator use, mechanical failures averaged once every 8,950 (5,842 median) hours, and operator errors averaged once every 12,158 (7,788 median) hours.

When comparing the relative frequency of malfunctions, mechanical failures, and operator errors, several statistically significant differences were noted within each category. The CUB for instance, operated significantly more hours before experiencing some sort of malfunction, compared to the VIP and 6400ST; the STAR operated successfully for longer than the 6400ST; the 7200ae operated longer than the VIP or the 6400ST; and the 8400STi operated longer than the STAR, VIP, 6400ST, or 7200ae (Fig. 1). The CUB was also significantly less likely to fail (or was more reliable) than either the STAR, VIP, or 6400ST. The 7200ae was more reliable than the STAR or the 6400ST. The 8400STi was more reliable than the STAR, the VIP, or the 6400ST (Fig. 2). The STAR was less likely to experience an operator error than the CUB, the VIP, the 6400ST, or the 7200ae. The 7200ae experienced fewer operator errors than the VIP. The 8400STi experienced fewer operator errors than the CUB, the VIP, the 6400ST, or the 7200ae (Fig. 3).

Purchase prices ranged from a low of $9,290 to a high of $28,865 (Table 2). Except for the CUB, which cost $5,600 for each 10,000 hours of use, preventive mainte-

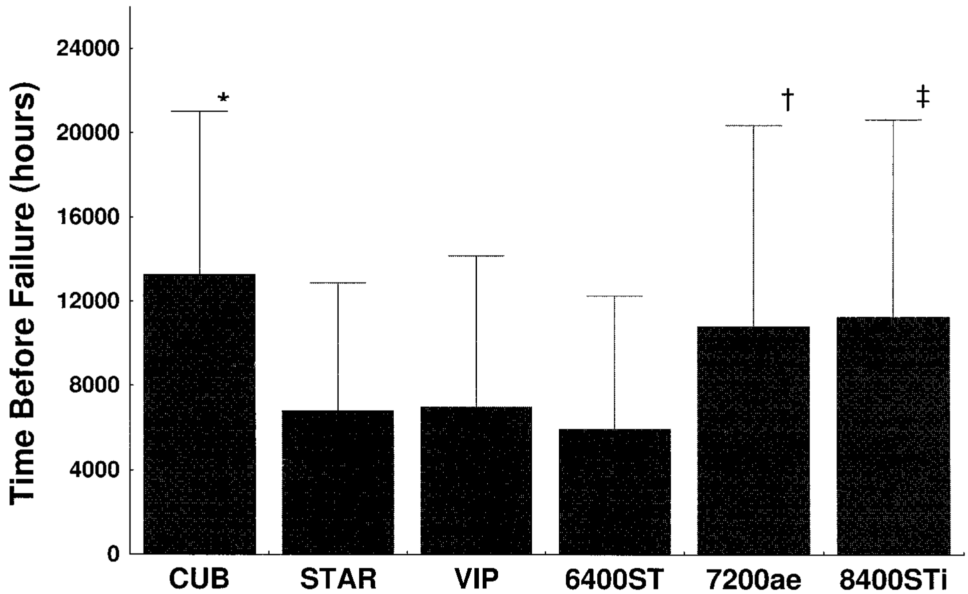

Fig. 2. Hours of ventilator operation before experiencing an unexpected mechanical failure (time before failure) for each of the 6 ventilator brands studied. Data are mean ± SD. CUB = Bear Cub Infant ventilator. STAR = Mallinckrodt Nellcor Puritan Bennett Infant Star ventilator. VIP = Bird VIP ventilator. 6400ST = Bird 6400ST ventilator. 7200ae = Mallinckrodt Nellcor Puritan Bennett 7200ae ventilator. 8400STi = Bird 8400STi ventilator. * $p < 0.05$ compared to the STAR, VIP, and 6400ST. † $p < 0.05$ compared to STAR, and 6400ST. ‡ $p < 0.05$ compared to STAR, VIP, and 6400ST.

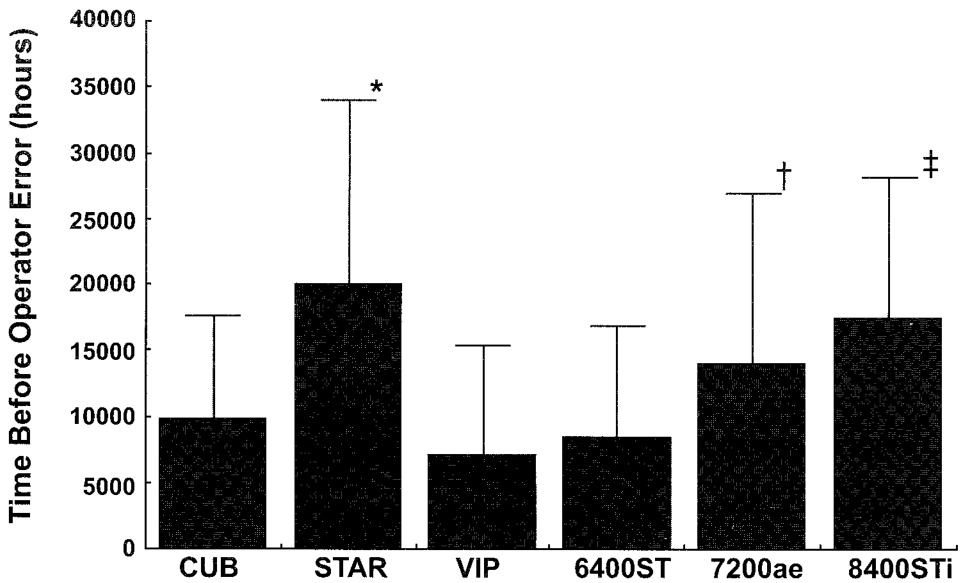

Fig. 3. Hours of ventilator operation before experiencing an unexpected operator error (time before operator error) for each of the 6 ventilator brands studied. Data are mean ± SD. CUB = Bear Cub Infant ventilator. STAR = Mallinckrodt Nellcor Puritan Bennett Infant Star ventilator. VIP = Bird VIP ventilator. 6400ST = Bird 6400ST ventilator. 7200ae = Mallinckrodt Nellcor Puritan Bennett 7200ae ventilator. 8400STi = Bird 8400STi ventilator. * $p < 0.05$ compared to CUB, VIP, 6400ST, and 7200ae. † $p < 0.05$ when compared to VIP. ‡ $p < 0.05$ compared to CUB, VIP, 6400ST, and 7200ae.

nance costs exhibited less range, between $1,865 and $3,063 for each 10,000 hours of use (see Table 2).

Time series data clearly show that even as the average age of the 75 ventilators increased from 3.71 to 8.57 years, the number of mechanical failures and operator errors experienced each month remained nearly constant (Fig. 4), despite increased utilization of the 75 ventilators. The average number of patient days of mechanical ventilation billed by the hospitals increased from 1,067 to 1,367 days per month (see Fig. 4).

Table 2. Ventilator Purchase Price and Long-Term Maintenance Costs by Ventilator Type

Ventilator brand	Purchase price (in 1999 $)	Maintenance cost per 10,000 h ($)	Maintenance cost per 50,000 h ($)	Total cost at 50,000 h ($)
CUB*	9,250	5,600	28,000	37,250
STAR	11,985	2,925	14,625	26,610
VIP	16,380	3,063	15,315	30,695
6400ST	9,290	2,800	14,000	23,290
8400STi	16,830	3,000	15,000	31,830
7200ae	28,865	1,865	9,325	38,190

*No longer commercially available. Price is in 1996 dollars. CUB = Bear Cub Infant ventilator; STAR = Mallinckrodt Nellcor Puritan Bennett Infant Star ventilator; VIP = Bird VIP ventilator; 6400ST = Bird 6400ST ventilator; 8400STi = Bird 8400STi ventilator; 7200ae = Mallinckrodt Nellcor Puritan Bennett 7200ae ventilator.

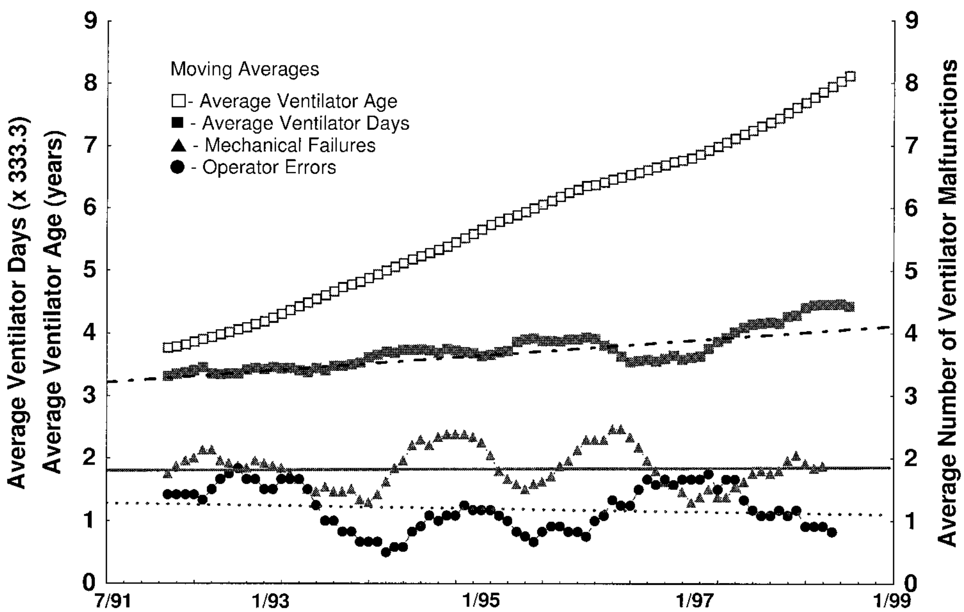

Fig. 4. Time series plot depicting variations in ventilator age (open squares), number of ventilator days billed by the hospital (squares), number of mechanical failures experienced each month (triangles), and number of operator errors experienced each month (circles) for the entire 90-month duration of the study. Superimposed on the time series data are best-fit trend lines, fitted using the least squares technique. Trends in number of ventilator days billed by the hospital each month (dashed line), number of mechanical failures each month (solid line), and number of operator errors experienced each month (dotted line) are shown. Data are centered, 12-month moving averages.

Discussion

Primary findings of this study include: (1) modern mechanical ventilators, when used and monitored carefully, appear to be extremely safe. In over 2,000,000 hours of ventilator use no documented instances of long-term patient harm followed any of the 282 reported malfunctions. (2) There are significant differences in the frequency of mechanical failures, operator errors, and total malfunctions among the 6 ventilator brands studied. (3) There are differences in the long-term maintenance costs associated with modern ventilators, and large differences in purchase price. (4) Modern mechanical ventilators do not seem to experience an increased incidence in any type of malfunction as they age, despite an increased utilization. In fact, these data suggest they may become more reliable with increasing age. (5) If these 75 ventilators are representative of ventilators in general, modern mechanical ventilators may be as prone to human errors as were their predecessors.

To my knowledge, data describing ventilator use and malfunctions, as presented in the Results and Table 1, are unique. Thus, these findings cannot yet be compared to others. The 2,201,771 hours of ventilator operation without documented long-term patient injury is noteworthy, but without comparable data on earlier vintage ventilators we cannot validate manufacturer claims that modern mechanical ventilators are safer.

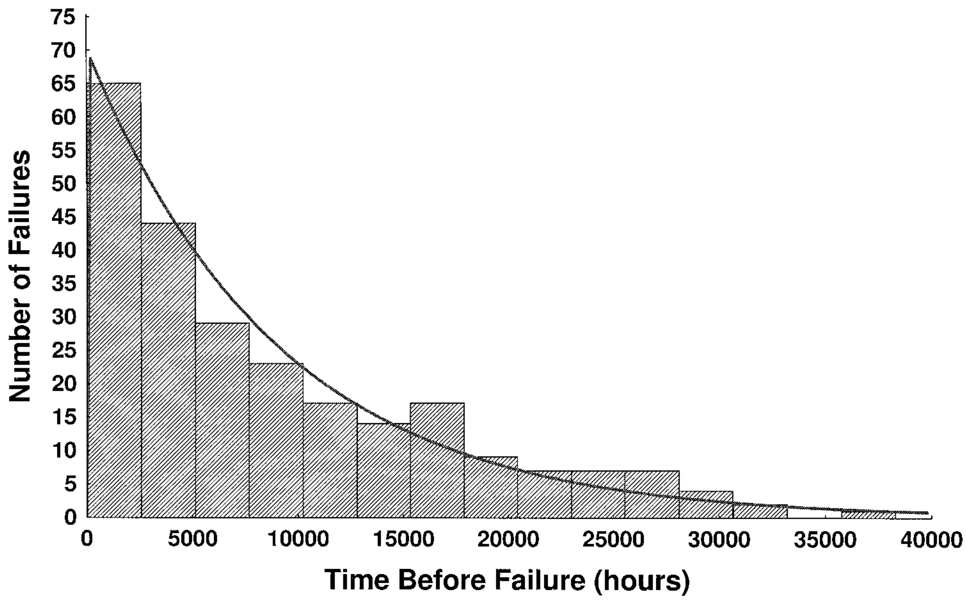

Fig. 5. Histogram plotting a series of 15 time intervals before mechanical failure against the number of ventilators experiencing mechanical failure within each time interval during the study. As expected for failure or survival times, data show a decidedly exponential or Weibull dispersion (as compared to Gaussian or normal dispersion). A representative exponential curve, of the form $y = ae^{-bx}$ is shown, where a and b are constant parameters of the distribution.

As noted, significant differences were found in the frequency of total malfunctions, mechanical failures, and operator errors experienced by some of the 6 ventilator brands. Such data could prove useful to someone considering which ventilator brand to purchase. For instance, the CUB was significantly less likely to experience a mechanical failure than the other infant ventilators (STAR, VIP). Or, if trying to decide between a 7200ae and 8400STi, it might be useful to note that while these 2 ventilators are *not* different in terms of mechanical failures, the 8400STi is significantly less likely to experience downtime as a result of operator errors.

The 75 ventilators included in this study represent, by definition, a convenience sample. Obtaining a truly independent and random sample could prove problematic, even with a multi-institutional study. Hospitals often utilize completely individualistic mixes of different types of ventilators, do not keep their own records, and buy ventilators in large quantities to save money, all of which make obtaining an independent and random sample difficult. Furthermore, a variety of factors affect the operating environment of a ventilator (including the frequency of electrical interruptions, brownouts, or water or other contamination in the compressed air) and would likely vary from one hospital to another. It would be unfair to compare a brand operated in a hostile environment to another brand operated under nearly optimal conditions. For these and other reasons (mentioned later), the reader is cautioned against placing too much importance on the exact times before malfunction, failure, or operator error. Nevertheless, although the exact hours before a malfunction might represent a questionable value, the *trends* observed are likely more reproducible because, though the operating environment and other factors vary from one institution to another, these factors remain consistent for each ventilator and brand of ventilator operating at each hospital. Therefore, regardless of the absolute number of hours measured before malfunction, if the CUB was more reliable than the STAR in one hospital, that trend is likely to be repeated elsewhere, regardless of the operating environment.

The astute observer may have noticed that some of the standard deviations (SD) are actually *larger* than the associated mean values (see Figs. 1–3). If these data were normally distributed, this situation would indicate extreme variance and very poor or possibly useless samples. However, failure or survival data such as this generally assumes exponential or Weibull dispersion (Fig. 5).[12] Such dispersion patterns always produce large SDs, and in some cases the SD exceeds the magnitude of the mean. Rather than attempt to explain such wide variances, some statisticians opt to report the median of such data sets, thereby avoiding the use of SDs altogether. Recognizing that most readers are more familiar with the concept of the mean and SD, and that the absolute values are of questionable importance, I have reported comparative values using the more traditional mean and SD. Whenever possible, the median value is also included parenthetically.

The decision to include censored observations and analyze these data using an obscure survival analysis technique may have confused some readers. As mentioned

Table 3. Comparison of Descriptive Statistics for Ventilator Failures, With and Without Censored Observations

	Mean hours before failure (with/without)	Median hours before failure (with/without)
CUB	13,257/12,983	13,203/14,833
STAR	6,927/5,490	4,849/3,686
VIP	6,996/5,351	4,999/3,743
6400ST	5,916/6,078	2,997/2,801
7200ae	10,749/8,700	8,973/5,304
8400STi	11,199/9,229	8,664/5,728
Total	8,950/7,562	5,842/4,844

CUB = Bear Cub Infant ventilator; STAR = Mallinckrodt Nellcor Puritan Bennett Infant Star ventilator; VIP = Bird VIP ventilator; 6400ST = Bird 6400ST ventilator; 7200ae = Mallinckrodt Nellcor Puritan Bennett 7200ae ventilator; 8400STi = Bird 8400STi ventilator.

previously, excluding censored data can bias a study's results; these data proved no exception. To demonstrate this fact, data gathered on the number of hours ventilators operated before experiencing a mechanical failure were analyzed twice. The initial analysis *included* the censored observations and the second analysis *excluded* the censored observations (Table 3). Using Table 3, several important inferences can be made. First, with only two exceptions, each brand of ventilator had a longer mean and median survival time when censored observations were included; thus, without the censored observations, we would have been misled into believing that the ventilators failed, on average, sooner than they actually did. By definition, a censored observation means the ventilator was still functioning at the conclusion of the study, and that the ventilator continued to function for an indeterminate additional period of time following conclusion of the study, which means that average survival time, including censored data, still *underestimates* the actual time before failure. An unexpected and statistically improbable finding made evident by Table 3 is that virtually all the comparisons (12 of 14, or 86%) exhibited longer mean (6 of 7) and median (6 of 7) times when the censored observations were included. If this finding is valid (ie, not a chance observation), then the data suggest that, on average, these ventilators were becoming less likely to fail as they aged. Collateral substantiation for this concept is found in two places: (1) the time series data, which shows that, despite increased utilization and age, ventilator malfunctions per month remained essentially constant throughout the study (see Fig. 4), and (2) the repair manual for the STAR, which specifically alludes to an "increased reliability with age."[13] The prospect that the measured time before failure of a ventilator might change as a function of time provides yet another reason for not placing too much emphasis on the exact times produced by this study. Moreover, if this information proves reproducible and accurate, hospitals could save money by maintaining ventilators longer before replacing them.

With new ventilators costing $30,000 or more, repairs $1,000 or more,[9,10] and with very high long-term maintenance costs (see Table 2), purchasing, owning, and maintaining a fleet of modern ventilators is a very costly proposition. Data such as these, if coupled with similar data gathered on other common ventilators, could eventually provide hospitals with a powerful tool for optimizing the dollars spent providing mechanical ventilation. It is surprising in this era of cost-containment that more administrators and institutions are not asking for unbiased, scientific comparisons.

These data also suggest that we have made little or no progress in reducing operator errors during mechanical ventilation. In this study, operator errors accounted for 38% (106 of 282) of reported malfunctions. This figure is quite comparable to two previous studies, in which operator or human errors associated with mechanical ventilation accounted for 40% and 31% of the total malfunctions, respectively.[14,15]

Human errors are potentially as dangerous as any type of malfunction,[7,8] yet they are the most preventable. These data represent a useful historical benchmark,[16] underscoring the need for improvements. If we are to reduce operator errors, particularly in an era preoccupied with cost-containment strategies, we must ensure that only conscientious practitioners with the necessary expertise are allowed to manage patients requiring ventilatory support. Should we fail to do so, a concomitant rise in the frequency and severity of operator errors seems inevitable.

Conclusions

In conclusion, these data suggest that most modern mechanical ventilators are rugged and safe. However, they are not comparable in terms of unexpected malfunctions. Furthermore, though ventilator malfunctions are to some extent inevitable, it appears that we have done very little over the years to limit or reduce the frequency of malfunctions. If hospitals considered unbiased, comparative, scientific data before deciding which ventilators to buy, substantial sums of money could be saved and malfunctions avoided. Modern ventilators also appear to become increasingly reliable the longer they are used, which is contrary to the popular notion that ventilators cost more to maintain as they age.[10] If these data can be validated, they may prove financially useful when considering whether to purchase new ventilators or continue to maintain older ones. Finally, the lack of unbiased scientific data of this type makes comparing and validating these data difficult, and suggests additional research and publication on the subject.

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PRODUCT SOURCES

Ventilators:

Bear Cub Infant Ventilator, Bear Medical Products, Thermo Respiratory Group, Yorba Linda CA

Bird VIP Ventilator, Bird 6400ST Ventilator, and Bird 8400STi Ventilator, Bird Medical Products, Thermo Respiratory Group, Yorba Linda CA

Mallinckrodt Nellcor Puritan Bennett 7200ae Ventilator, and Infant Star Ventilator, Mallinckrodt Nellcor Puritan Bennett Corporation, St Louis MO

Software:

Statistica for Windows 95/98/NT, version 5.1(M), StatSoft Inc, Tulsa OK

REFERENCES

1. Mushin WW, Rendell-Baker L, Thompson PW, Mapelson WW. Automatic ventilation of the lungs, 3rd ed. Oxford: Blackwell Scientific Publications, 1980: 184.
2. Mushin WW, Rendell-Baker L, Thompson PW, Mapelson WW. Automatic ventilation of the lungs, 3rd ed. Oxford: Blackwell Scientific Publications, 1980: 203.
3. Bone RC. Acute respiratory failure. In: Burton GG, Hodgkin JE, Ward JJ, editors. Respiratory care: a guide to clinical practice, 3rd ed. Philadelphia: JB Lippincott, 1991.
4. Watson H, MacIntyre NR. Mechanical ventilator failure. In: Fulkerson W, MacIntyre NR, editors. Vol 4. Problems in respiratory care: complications of mechanical ventilation. Philadelphia: JB Lippincott, 1991: 127–135.
5. MacIntyre NR. Mechanical ventilation: the next 50 years. Respir Care 1998;43(6):490–493.
6. Feeley TW, Bancroft ML. Problems with mechanical ventilators. Int Anesthesiol Clin 1982;20(3):83–93.
7. Klein EF Jr, Graves SA. "Hot pot" tracheitis. Chest 1974;65(2):225–226.
8. Hall MW, Peevy KJ. Infant ventilator design: performance during expiratory limb occlusion. Crit Care Med 1983;11(1):26–29.
9. Kacmarek RM, Meklaus G. Microprocessor-controlled mechanical ventilators. In: Banner MJ, editor. Problems in critical care, Volume 4 (2). Philadelphia: JB Lippincott, 1990:161–183.
10. Kacmarek RM. Introducing new mechanical ventilation technology: the hospital perspective. Respir Care 1995;40(9):947–951.
11. Mantel N. Ranking procedures for arbitrarily restricted observation. Biometrics 1967;23(1):65–78.
12. Kleinbaum DG. Survival analysis: a self-learning text. Ann Arbor MI: Springer-Verlag, 1996: 13.
13. Infant Star service and repair instructions. Form No. 9910103. San Diego CA, 1988: I-2.
14. Abramson NS, Wald KS, Grenvik ANA, Robinson D, Snyder JV. Adverse occurrences in intensive care units. JAMA 1980;244(14):1582–1584.
15. Zwillich CW, Pierson DJ, Creagh CE, Sutton FD, Schatz E, Petty TL. Complications of assisted ventilation: a prospective study of 354 consecutive episodes. Am J Med 1974;57(2):161–170.
16. Chatburn RL, El-Khatib M, Blumer JL. Benchmark data for the outcome of mechanical ventilation in a pediatric intensive care unit. Respir Care 1997;42(2):221–225.

APPENDIX

Analysis of Survival Data

Quantitative analysis of survival time data generally involves the determination of 2 related functions: the survivor function, and the associated hazard function. By definition, the survivor function, S(t), gives the probability that a ventilator survives longer than some specified time (t). Theoretically, as t ranges from 0 to infinity, graphs of survivor functions assume a smooth curve with the following characteristics: (1) they do not increase (ie, the proportion surviving always decreases as time increases); (2) at t = 0, S(t) = S(0) = 1, or because at the start of the study no ventilators have failed, the probability of surviving past t = 0 is 1; and (3) when t = infinity, S(t) = S(infinity) = 0, or if t is increased without limit, eventually no ventilator survives. The associated hazard function, h(t), is defined as the limit, as Δt approaches 0, of a probability statement about survival, divided by Δt (Δt represents a very small increment of t). Conceptually, the hazard function gives the instantaneous potential per unit t for the terminal event (failure) to occur, given that the ventilator has already survived up to t. As with the survivor function, hazard functions can be graphed with respect to t. However, unlike the survivor function, the related hazard does not have to start at 1 and decrease to zero. On the contrary, the hazard function can start anywhere, go up, down, or in any direction over t. Important characteristics of hazard functions are as follows: they are always ≥ 0, and they have no upper bound. Because S(t) provides us with quantitative information regarding survival and h(t) information about failure, then in some sense the hazard function can be considered as the negative side of information provided by the survivor function. Stated in practical terms, the higher S(t) for a given t, the lower h(t), and vice versa.

When analyzing survival data, the shape or form of the associated hazard function is used to determine the appropriate survival model. By definition, whenever the hazard function is constant [ie, h(t) = constant = b], the survival model is said to be exponential, ie, $S(t) = ae^{-bt}$ (a is a constant parameter of the distribution). For instance, imagine we studied the survival within a group of normal human subjects over a 2-year period. Because the subjects are all healthy, their risk of dying remains essentially constant throughout the course of the study; the associated hazard function would be constant and the best survival model would therefore be exponential. On the other hand, if the hazard function increases or decreases as a function of time, the survival model is referred to as either an increasing or decreasing Weibull model, respectively. If a hazard function first increases then decreases, the survival model is best defined as lognormal. The Weibull survival models are simply weighted exponential models of the form $S(t) = abt^{b-1}e^{-at^b}$, where a and b are constant parameters of the distribution. Algebraically, the Weibull model reverts to the exponential model whenever the b weight = 1.