ANEROID SPHYGMOMANOMETERS: DO THEY NEED REGULAR INSPECTION?

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ABSTRACT

Aneroid sphygmomanometers are some of the simplest, yet vital, diagnostic medical devices still used in healthcare. They have been used for blood pressure measurements for decades because of their simplicity. Although they fall under the classification of medical equipment, their management generally varies from other medical equipment because they are simple and mechanical.

A number of departments that manage aneroid sphygmomanometers rely on users to report inaccuracies. In most cases they are not tested regularly because it is assumed that they are reliable. However, a number of studies have shown that aneroid sphygmomanometers are susceptible to linearity errors. This paper presents results of a study that was undertaken in the Winnipeg Regional Health Authority to establish how aneroid sphygmomanometers are managed and whether they need to be placed on a regular inspection program. Results from other facilities in Canada are also presented for comparison.

INTRODUCTION

Measurement of blood pressure is a routine clinical diagnostic method for assessing and monitoring patients' cardiovascular risk. Several instruments can be used for non-invasive blood pressure measurement. These are mercury manometers, aneroid sphygmomanometers and automatic noninvasive blood pressure (NIBP) monitors. While automatic NIBP monitors are regularly inspected, like other medical equipment, to maintain accuracy, aneroid sphygmomanometers are in most cases left out of regular maintenance and serviced only during repair. However, the accuracy of the aneroid sphygmomanometers, which for the most part have replaced mercury manometers, is equally important because they provide vital diagnostic information.

While literature suggested that aneroid sphygmomanometers needed regular inspection, it was found that there was no clear reason why the facilities in our Region did not have the devices on regular inspection; save one facility that had done studies some years back which suggested that the devices did not need regular inspection. The conflicting information, the inconsistent management of aneroid sphygmomanometers and the need for our Region to have a clear rationale for either including or excluding the devices from regular inspection prompted the study and review of systems in other Canadian hospitals.

METHODS

To determine the status of the aneroid sphygmomanometers in our health region, an inspection protocol and test chart were developed for the study. The aim was to inspect a substantial sample from each of the nine facilities within the study time period. The sample size from each facility could not be determined ahead of time because of limited records.

In order to identify all the different types of failures, two main failure types were defined; physical failure (which included broken face glass, frayed tubing, indicator needle out of "zero box/cal") and performance failure (which was tested at 40±3 mmHg, 120±3 mmHg and 200±3 mmHg). The ±3 mmHg error is based on AAMI standard. [1] In order to count all the types of failures, the inspector was required to perform all the inspections, except in cases where it was not possible to proceed, such as inability to do performance test because of a gross leak.

A literature search was conducted on the subject of accuracy of aneroid sphygmomanometers to determine other researchers' findings.

A questionnaire was also sent to hospitals on the CMBES list serve to determine how they manage their aneroid sphygmomanometers.

RESULTS

Regional cases

The results presented are for eight out of the nine facilities because the one facility indicated that

they still use only mercury manometers. The results concerning management of the aneroid sphygmomanometers from the eight facilities are presented on Table 1. The results show that the departments responsible for managing these devices vary from facility to facility. The decision whether to inspect these devices regularly or not does not seem to depend on who is managing these devices – they are consistently serviced on as need basis.

The results of the inspection are presented on Table 2. These results are only for devices where the inspector performed all the inspection tests for each device as per the study methods. That is, the table presents information for only devices that were fully tested to identify all the failures on each device. The total number of fully tested devices was 451.

There were however some devices that were not fully tested, i.e. the inspection was done only up to the first failure. For these devices, it was not possible to count all the faults and therefore these devices are not included in the detailed analysis in Table 2. The total number of devices not fully tested was 75.

Therefore, the total number of devices inspected was 526. From the count, the total number of devices that failed the inspection was 107(20.3%), which included both fully inspected and partially inspected devices.

Examining data for fully tested devices, only 32(7.1%) of the devices failed the inspection. Out of the 32 that failed the inspection, 30(93.8%) failed with performance faults. Out of the 30 performance failures, 22(73.3%) were not attributed to any physical fault. [2] Thus, the majority of the performance failures could not be predicted without testing.

Analysis of the performance error margins, for those devices where the test measurements were recorded, suggests that some devices were grossly out of specification. It was found that most of the performance failures occurred at 120 and 200 mmHg. [2] This is significant because it is in the clinical measurement range for adults.

Analysis of published studies

Studies have shown that aneroid sphygmo-manometers can be equally accurate and reliable when compared to mercury manometers, but need to be maintained to retain accuracy and reliability. [3, 5]

Comparison of regularly inspected aneroid sphygmomanometers and devices with no regular inspection has shown that regularly maintained devices can be reliably used for accurate blood pressure measurement. [6, 11] Device inaccuracies may give high or low blood pressure readings, which may affect patient treatment. [7]

Cases from the survey

Responses were received from only four hospitals. The results of the management survey are presented on Table 3. Data shows that the department responsible for the aneroid sphygmomanometers varies from facility to facility.

Table 4 is the result of the inspection from one hospital. Unfortunately at the time of completing this paper other facilities had not sent their inspection data. The data will be presented when available. This hospital had 90.9% of the inspected devices fail the inspection. Of these, 30% had performance faults. Some of the performance faults were related to physical faults and most of the gross errors occurred where there was an obvious physical fault.

DISCUSSIONS

Accurate measurement of blood pressure is vital for the patient; a correct diagnosis of hypertension is essential. Consistently underestimating diastolic pressure by 5 mmHg could result in hypertensive individuals being denied potentially life-saving treatment [4]. And consistently overestimating diastolic pressure by 5 mmHg could result in individuals being wrongly diagnosed as hypertensive and being inappropriately treated. [4]

Several factors affect the accuracy of blood pressure measurement. These factors can be categorized under three main groups - the patient, the technique and the measurer. [10] While the effects of these factors can be minimized by the clinician, there is yet another factor, the equipment itself, [12] whose effect on accuracy of blood pressure can be minimized by maintenance. [3, 5] Here the clinician's role is limited to identifying physical defects.

Device physical defects such as indicator needle outside "zero box", cracked face plate and defective tubing may contribute to measurement inaccuracies. [8] However, it has been shown that aneroid inaccuracies are sometimes due to linearity errors. [9] This means that the fact that the initial position of the needle may be in the "zero box", does not mean that the device will read accurately in the whole range of interest.

The results of the study have shown that the majority of performance failures were not related to any physical fault and therefore could not be detected by users without testing the devices. It is important to note that most linearity errors were found to occur in a clinically significant measurement range. This corroborates the other previous studies; that linearity errors do occur in aneroid sphygmomanometers.

Unfortunately the survey produced limited results but the limited data shows that there were units that were in use but with some faults.

All the factors that affect the accuracy of blood pressure measurement have cumulative effect on the measurement error. Thus, the equipment factor can still have its effects on measurement even if all the other factors are reduced. Therefore, to increase measurement accuracy, all factors must be reduced.

There is ample evidence to suggest that aneroid sphygmomanometer need regular inspection. The inspection frequency period cannot be established from this data. Any frequency will be determined taking into account all the factors in a particular facility. It is also important to note that user education is key in ensuring that they vigilantly report any physical faults. As a result of this study, the decision was to place all aneroid sphygmomanometers on regular inspection.

In terms of management, it is important for those in the clinical engineering service to consider the importance of these devices. They are part of medical equipment and should be managed with the same guidelines regardless of who is managing them. Even if they are managed by non-CE maintenance department it is important for clinical engineering to assist them to appreciate the importance of keeping these devices accurate.

Study limitations

The age of the devices could not be easily determined because there were no easily available inventory records. Therefore, it was not possible to determine the relationship between the loss of linearity and age of device and/or amount of usage.

The number of devices from each facility was not known so it was not possible to determine what percentage of each facility inventory was inspected during the study.

Unfortunately there was limited response from Canadian hospitals and therefore meaningful country-wide comparison could not be done.

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Table 1. Aneroid Management in the Study Region

Facility	Managing dept.	Regular inspection	Reason for inspecting or not inspecting	Inventory tracking
1	Clinical Engineering (CE)	No	Depend on dial position. Therefore, should be covered by repair	No
2$^{\alpha}$	Property Services	No	Do not know when new units ordered. Just find them in wards.	No
3	Physical Plant	No	No safety issue. Users would report if not calibrated	No
4	Maintenance	No	Medical equipment – do not inspect medical equipment	No
5	CE and Physical Plant	No	Units 4 – 5yrs old so felt new and repair would do	No
6$^{\alpha}$	Maintenance	No	New units, also waiting for regional guidance	No
7	Clinical Engineering	No	Historical – no change of practice after replacement of mercury manometers	No
8	Clinical Engineering	No	Have not been instructed to inspect. Have always done them on breakdown repair	No

$^{\alpha}$ Facilities do not have clinical engineering service

Table 2. Aneroid Inspection Results for the Study Region

Facility	# Units inspected	# Units failed	# (%) Units with performance faults	Failures by type		Error range from test point (mmHg)	Errors range from test point (%)
				Physical[β]	Performance[χ]		
1	16	3 (18.8%)	2 (66.7%)	3	2	4 to 12	2.5 to 10
2	16	6 (37.5%)	6 (100.0%)	4	6	4 to 13	2.5 to 32.5
3	33	3 (9.1%)	2 (66.7%)	3	2	4 to 5	2 to 2.5
4	195	14 (7.2%)	14 (100.0%)	0	14	8 to 10, unknown[ϕ]	4 to 25
5	20	1 (5.0%)	1 (100.0%)	0	1	unknown	unknown
6	27	1 (3.7%)	1 (100.0%)	1	1	6	3
7	40	1 (2.5%)	1 (100.0%)	0	1	7	17.5
8	104	3 (2.9%)	3 (100.0%)	0	3	unknown	unknown
TOTAL	**451[δ]**	**32 (7.1%)**	**30 (93.8%)**	**11**	**30**		

[β] Physical failure includes broken face glass, frayed tubing, indicator needle out of "zero cal".

[χ] Failure at any or all the three test points (40, 120, 200mmHg) for each device was counted as one failure.

[δ] Total fully inspected devices to identify all failures. There were additional 75 partially tested devices that failed; total inspected devices is 526.

[ϕ] Unknown means the test readings were not recorded but only indicated that it was out of specification.

Table 3. Aneroid Management from the Survey

Facility	Managing dept.	Regular inspection	Reason for inspecting or not inspecting	Inventory tracking	Comments
1	Splint Room (under Distribution Dept.)	No. 15% sample inspection once a year[λ]	Inspection recommendation from AHA or AAMI. BME has no stewardship of the devices	No	Still to provide test results
2	CE and Maintenance	No	Resources devoted to repair and PM of critical equipment	Yes	Results provided
3	Maintenance	No	No test equipment	No	Still to provide test results
4	Maintenance	?	Mechanical devices – Maintenance responsibility	No	

[λ] Couple of failures at 1yr by 4mmHg at 150mmHg. Devices relatively new - 2003.

Table 4. Aneroid Inspection Results from the Survey

Facility	# Units inspected	# Units failed	# (%) Units with performance faults	Failures by type		Error range from test point (mmHg)	Errors range from test point (%)
				Physical	Performance		
2	11	10 (90.9%)	3 (30.0%)	11	5	4 to 20	2 to 42.5
TOTAL	**11**	**10 (90.9%)**	**3 (30.0%)**	**11**	**5**		

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