Original Article

Calibration-Related Knowledge and Sensitivity Levels of Healthcare Staff Using Medical Devices

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Abstract

Background: Calibration of medical devices used is critical in terms of health and safety of patients and employees. The findings obtained in the study aimed to determine the knowledge and sensitivity of the health care staff using medical devices regarding the concept of calibration.

Methods: The sample size of the study consisted of 262 healthcare professionals who worked at the institution. Individual Information and "Medical Device Calibration General Evaluation for Medical Device Users" surveys were used as data collection tools. Mann Whitney U, Kruskall Wallis tests, and correlation analyses were completed.

Results: Although 93.1% of the participants used more than one medical device, 57.6% stated that they did not receive calibration training for these devices. According to the calibration training status, there was a significant difference between calibration evaluation scores ($Z=-5.02$, $p<0.001$). In terms of educational status, there was a significant difference in the calibration evaluation scores ($U=7049$, $Z=-2.37$, $p=0.018$) between undergraduate/graduate and associate degree program/high school graduates. A significant relationship was found between working time in the current institution and the total score ($r=0.157$, $p=0.01$), and the total working time in the profession and the total score ($r=0.129$, $p=0.03$). Physicians' calibration awareness sub-dimension score was higher than the other two groups ($X^2(2)=8.11$, $p=0.017$). In the evaluation made within the group, the technician group had higher scores than the other groups ($X^2(2)=14.86$, $p=0.01$).

Conclusions: Therefore, including this subject in the curricula of healthcare worker candidates and continuing in-service training for employees can indirectly contribute to the quality and safety of healthcare.

Keywords: Calibration, Medical device, Attitude, Health personnel

Introduction

Healthcare services consist of complex structures that use both manpower and technology. In other words, it is clear that technology is as important as the labour-intensive structure in healthcare processes. Care, repair and calibration concepts are among the important issues to be emphasized due to the recent advancements of medical technology used in healthcare, the desire to reach the standards of developed countries in the field of health, the importance that the patient safety concept gained, and studies on quality and accreditation (Ozgules et al., 2015). Therefore, calibration of medical devices used is critical in terms of health and safety of patients and employees. Calibration is a set of measurements used to measure the accuracy of other tests and measuring instruments, and to determine and document their deviations using a measurement standard or a system of known accuracy under specified conditions (Biyokam, 2020). For example, the accuracy of sphygmomanometer measurements is determined and documented by authorized personnel with the calibrator approved for this work under the ambient conditions required for the calibration of the

sphygmomanometer (Republic of Turkey Ministry of National Education, 2012).

In relation to this subject matter, the Republic of Turkey Ministry of Health, has issued a guide titled "Biomedical Metrology Operations Guide" in 2014. In this guide prepared by the Public Hospitals Administration of Turkey, Clinical Engineering Management Unit, the whole procedure is explained in detail from the conditions of the purchase of calibration services to procedures needed to be done following the measurement (Cihan et al. 2020). It also includes regulations on the correct and reliable use of medical devices to protect patient health and ensure the safety of the healthcare worker. The "Regulations on Testing, Control and Calibration of Medical Devices" addressing accurate and reliable use of medical devices with the purpose of protecting patients' health and safety of healthcare workers was published in the Official Gazette dated 25.05.2015 and numbered 29397. These regulations that regulate the medical device sector significantly include topics on procedures for testing, control and calibration of medical devices, the working principles of calibration institutions, staff qualifications, and the suitability of the equipment owned. These regulations address the provisions through, at least, once a year audits of the organizations operating in the sector with the purpose of having the test, control and calibration procedures of medical devices performed by qualified technical personnel (Republic of Turkey Ministry of Health, 2015).

Medical device calibration is the determination and reporting of whether medical devices in health institutions function properly or not. Calibration is not adjustment or repair. Accuracy of measurements by a repaired or adjusted device can be determined by calibration (Republic of Turkey Ministry of National Education, 2012).
Causes of medical device errors can be grouped as due to improper use of devices, faulty devices, or improper settings. A report published by the World Health Organization in 2005 states that more than half of medical devices in developing countries are not functioning properly (WHO 2010). The main purposes of calibration in medical devices are:

- Ensuring complete work
- Extending life economically
- Reducing service costs
- Ensuring efficient use
- Efficient workforce in terms of staff
- Increasing patient satisfaction
- Increasing the quality of health services (Gulec et al. 2009).

As stated in the purpose of the regulation, these services are arranged to ensure that patients, users and third parties are protected against the dangers that may arise in terms of health and safety during the use of medical devices (Republic of Turkey Ministry of Health, 2015). However, there are not many studies evaluating the knowledge and sensitivity of critical healthcare staff regarding calibration. It would not be possible to mention safety if health staff are not knowledgeable and sensitive about the calibration of these devices that are used frequently. In alignment with this, the hypotheses of our study are as follows:

H0: The demographic characteristics and working conditions of individuals have no effect on the calibration knowledge level and sensitivity.

H1: The demographic characteristics and working conditions of individuals have an impact on the level and sensitivity of calibration knowledge.

Aim

The aim of this study was to examine the evaluations of health staff using medical devices regarding the calibration of the devices. The findings obtained in the study aimed to determine the knowledge and sensitivity of the healthcare staff using medical devices regarding the concept of calibration.

Methods

Population and Sample of the Study: This descriptive study was conducted in a city center between February and March 2018. The population of the study consisted of health staff working at a Training and Research Hospital. Instead of sampling, all of the population (N=282) was included in the study. The sample size of the study consisted of 262 healthcare professionals who worked at the institution during the time of the study and agreed to participate in the study.

Data Collection Tools:Individual Information and "Medical Device Calibration General Evaluation for Medical Device Users" surveys were used as data collection tools.

Individual Information Form: This form consists of 11 questions to identify the independent variables including gender, age, educational status, marital status, institution, unit, working time, and calibration training of participants.

Medical Device Calibration General Evaluation Survey: Medical Device Calibration General Evaluation Survey for medical device users was developed by Kırsaç and Onder (2015). The survey instrument consists of 40 items. The survey instrument used a 5-point Likert scale with "5- Strongly Agree", "4- Agree", "3- Neutral", 2- Disagree", "1- Strongly Disagree". However, as the items "12", "20", "21", "28", "29" and "31" had negative meanings; they were reverse coded during the analysis phase. The survey has 12 sub-dimensions. The lowest score that can be received from the survey is 40 while the highest score is 200. As the score increases, the level of knowledge of the participants about calibration was evaluated positively. The "Cronbach alpha" internal consistency coefficient of the survey instrument" is 0.913 (Kırsac et al.2015). In our study consisting of 40 items, the Cronbach Alpha internal consistency coefficient was calculated as 0.87.

Data Collection: In order to conduct the study, ethics committee approval and institutional permission were obtained from the University's Clinical Research Ethics Committee with the decision dated 2018 and numbered 06/06. In addition, permission from Kırsac to use the survey instrument, and informed written consents from the healthcare staff who agreed to participate in the study were obtained. The data were collected by the researcher through face-to-face interview method using the Individual Information survey and the Medical Device Calibration General Evaluation survey.

Data Analysis: Data analysis was completed by using IBM SPSS 25.0 statistical software. Data were shown with mean±standard deviation. Mann Whitney U, Kruskall Wallis tests, and correlation analyses were completed.

Ethical considerations: The approval of the Ethics Committee (2018/06) and the permission of the institution were obtained prior to the research. The participants were given a written informed consent form in accordance with the Declaration of Helsinki and their verbal consent was obtained.

Results

84% of the participants in the study were female. The mean age was 36.7±8.3 (19-55), and more than half of the participants (58%) were under 40 years of age. The mean working time in the profession was 15.3±8.8 years, the mean working time in their current unit was 7±3 years, and 53.4% of the staff were nurses. It was seen that more than half of the employees (54.9) had an undergraduate education and higher. Although 93.1% of the participants used more than one medical device, 57.6% stated that they did not receive calibration training for these devices (Table 1).

Table 1. Sociodemographic characteristics of participants

		n=262	%
Gender	**Female**	220	84
	Male	42	16
Age categories	**19-39**	152	58
	40-55	110	42
Education level	**Vocational school of health**	34	13.0
	Associate degree	84	32.1
	Bachelor degree	130	49.6
	Postgraduate degree	14	5.3
Marital status	**Married**	194	74
	Single	68	26
Occupation	**Nurse**	140	53.4
	Midewife	56	21.4
	Doctor	22	8.4

	Technician	20	7.6
	Other (emergency, paramedic)	24	9.2
Department	**Service**	102	38.9
	Intensive care	27	10.3
	Operation room	15	5.7
	Laboratory, x-ray	38	14
	Other (emergency, policlinic etc)	80	30.5
Total term of office in department	**0-10 years**	205	78.2
	11-20 years	35	13.4
	21-30 years	22	8.4
Total term of office in profession	**0-10 years**	88	33.6
	11-20 years	87	33.2
	21-30 years	83	31.7
	30 years and over	4	1.5
Number of medical devices used	**Using multiple devices**	244	93.1
	Only one device	18	6.9
Calibration training status	**Trained**	111	42.4
	Untrained	151	57.6

The overall calibration evaluation mean score of the staff participating in our study is 145.6±17.3. The score to be taken from the survey is between 40-200 with low being between 40-104, medium between 104-136.4, and high between 136.4 and 200 (Kırsaç 2015).

Accordingly, it can be stated that the health staff participating in our study have a high score (close to the middle threshold) regarding calibration. The mean and maximum scores of the staff participating in the study from the sub-dimensions of the calibration general evaluation are presented in Table 2.

Table 2. Medical Device Calibration General Evaluation Form Subscale Points

Subscales (item numbers)	Mean (max)	SD (±)
1. Definition of calibration (1,3)	8.34 (10)	1.2
2. Benefits of calibration (2,39)	8.16 (10)	1.2
3. Calibration awareness (4,20,27,35,38,40)	21.23 (30)	2.9
4. Who is doing the calibration (5,17)	7.28 (10)	1.7
5. Responsibility of the user (6,13,14,15,16,25,26,32,36)	33.79 (45)	5.7
6. Calibration period and timing (7,8,9,10,11)	18.41 (20)	3.5
7. Problems in calibration (12,21)	5.52 (10)	1.8
8. Importance of calibration (18,19)	8.27 (10)	1.4
9. Calibration training(22,23)	7.11(10)	1.4
10. Psychological relationship between user and calibration(24,28,29,37)	12.38 (10)	2.1
11. Devices that are to be calibrated (30,31)	6.56 (10)	1.3
12. Calibration- quality correlation (33,34)	7.76 (10)	1.5

*12,19,20,26,29,30,31 number of items encoded vice versa.

According to the calibration training status, there was a significant difference between calibration evaluation scores (Z=-5.02, p<0.001). In terms of educational status, there was a significant difference in the calibration evaluation scores (U=7049, Z=-2.37, p=0.018) between undergraduate/graduate and associate degree program/high school graduates. A significant relationship was found between working time in the current institution and the total score (r=0.157, p=0.01), and the total working time in the profession and the total score (r=0.129, p=0.03). In terms of other variables, there was no significant difference in the total score.

Profession types were examined in three groups that are; 1. midwife-nurse, 2. physician, and 3. other (technician etc.). In the evaluation by profession types, the third sub-dimension of the survey which is awareness of calibration was analyzed with Kruskal Wallis and a significant difference was found between the groups. In the evaluation made within the group, there was a difference between the midwife-nurse and the physician groups. Physicians' calibration awareness sub-dimension score was higher than the other two groups ($X^2(2)=8.11$, p=0.017). In the examination by profession types, there was a significant difference between groups in the fourth dimension examining who makes the calibration. In the evaluation made within the group, the technician group had higher scores than the other groups ($X^2(2)=14.86$, p=0.01).

Discussion

The devices used in health services are complex devices that are necessary for the maintenance of life. An intense training process is required for use of medical devices. Within the context of patient safety, there are incorrect measurements in some devices which resulted in death. In order to avoid such situations that are destructive in impact and severity, all measurement devices used in hospitals should be calibrated in certain periods. A false measurement by a device would lead to wrong diagnosis which would lead to wrong treatment. Thus, the result would be uncomfortable for the patient and their relatives. It should be noted that any case that cannot be measured cannot be controlled (Kurutkan et al., 2014).

Although the healthcare workers who participated in our study do not perform calibration themselves, they should be knowledgeable about definition, benefit, and awareness of calibration, as well as being cognizant of their own responsibilities. Healthcare workers who understand the critical importance of medical devices they use would pay attention to quality and serve accordingly. For example, 18.3% of 350 healthcare staff in Cıvdı's study stated that the purpose of calibrating the medical device is to pass the audits only (Cıvdı 2014). This result shows that the staff does not understand the importance of calibration.

The overall calibration evaluations mean score of the staff who participated in our study was 145.6±17.3. In the study of Kırsac conducted with 280 people, the mean score received in the calibration general evaluation survey was 161.72±17.0 (Kırsac 2015). Accordingly, it was observed that the levels of attention and sensitive behaviour of the staff in our study were lower than Kırsac's sample. In Sezdi and Günes's study, 6.5% of nurses think that calibration measurements do not benefit the patient. This group that does not believe in calibration measurements would not pay attention to points that need to be taken into consideration during and after measurements which may negatively affect the workflow of calibration measurements. For example, staffs who think that calibration of the sphygmomanometer does not benefit the patient would not realize that he is taking an incorrect measurement and thus, would do a follow up on the patient incorrectly. With this wrong measurement, the patient will be exposed to more medications which would lead to the possibility of a wrong treatment (Sezdi 2017). It is possible for medical devices to provide accurate and reliable results through regular calibrations performed in accordance with proper techniques (Howarth and Redgrave 2008, Odacıoğlu 2008). Considering that a potential mistake or neglected matter in the healthcare sector can cost a human life, the necessity of calibration measurements of diagnostic and treatment devices is of great importance. Another dimension is the high cost of the devices. Since the cost of medical devices is very high, hospital administrations should determine the necessary policy and establish an organization for the correct use of the devices, maintenance, repair and calibration (Soylular 2006). Organization should include requirements for technical service and calibration of medical devices, software control, etc. (Ferreira 2011).

According to the information from personal communication and limited publications, it was observed that the meaning of calibration and metrology are not known by medical device users. Then, important issue becomes to educate and train medical people who are engaged in use of medical devices and measurements. Trainings must be given to medical device users in order to have them aware of metrological terms, importance and role of metrology and methodology of measurement and calibration (Karaböce et al., 2015). Approximately 30% of high-tech devices are out of use and at least 20% are used without maintenance and calibration due to lack of properly trained personnel (Tanyolac 1992). In the thesis study by Cıvdı, 44.9% of 350 health personnel stated that they needed training on medical device calibration (Cıvdı 2014). Half of the 150 medical device users in Soylular's study think that there is not enough training about the maintenance, safety and calibration of the devices (Soylular 2006).

In a study conducted by Sezdi and Günes focusing on the knowledge and views on calibration among nurses, it was found that only 35 of the 200 nurses received calibration training (Sezdi 2017). According to the results of our study, although almost all of the staff uses more than one medical device that requires calibration, more than half of them have not received calibration training. As stated in the findings, there was a significant difference between the scores of those who received medical device calibration training and those who did not shows that the awareness of the trainees on calibration (near the middle threshold) is high. In Sezdi's study, it was determined that there was a significant difference in the participants' knowledge of the green label according to their training status on medical calibration ($p<0.001$) (Sezdi 2017). In the study of Kırsac, whether or not the healthcare staff received calibration training was not questioned (Kırsac 2015). Thus, although there is not much data to be compared, it can be said that receiving training on calibration has a high potential to increase the knowledge and sensitivity about the subject. The training of medical device users should be organized in line with technological developments, planned, programmed and in certain periods by reorganization and all relevant personnel should be provided with this training (Tas and Selvi 2014). Calibration is critically important for patient safety, and thus, the goal should be to have high level of competency on calibration. The positive correlation between the education level and professional experience period of the hospital staff and the sensitivity score regarding calibration necessitates the planning of in-service training and activities.

Sezdi et al. reported that 3% of the nurses stated that calibration could be performed by the supplier company. Technical personnel, who are not in biomedical units in healthcare institutions, are not competent for this job. As employees of the supplier company cannot be objective in measurements of their own devices, calibration measurements should be performed by an independent calibration company or the biomedical staff of the hospital (Sezdi 2017). In our study, the mean score obtained from the fourth sub-dimension regarding who performed the calibration was found to be 7.28, and it can be said that there is not enough awareness on this subject.

Conclusions: The use of medical devices is becoming more and more common with the developing technology. Accurate and precise measurement/application of these devices depend on timely and accurate calibration. As the sensitivity of the health staff to the calibration of the medical device is important in terms of ensuring reliable results, the study results are considered to be important for the quality of care. Therefore, including this subject in the curricula of healthcare worker candidates and continuing in-service training for employees can indirectly contribute to the quality and safety of healthcare.

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