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Original Research

A Comparison of Efficacy, Safety and Cost Between MANTA™ and Proglide Vascular Closure Devices Following Transfemoral Transcatheter Aortic Valve Implantation

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ABSTRACT

Aims

Access site vascular complications remain a recognised complication following transcatheter aortic valve implantation (TAVI). Suture-based vascular closure devices (VCDs) such as ProGlide® (Abbott Vascular Inc., Santa Clara, CA, USA) are widely used in order to achieve rapid haemostasis. The MANTA™ (Essential Medical Inc., Malvern, PA, USA) is a collagen plug-based VCD which can be used as an alternative to traditional suture-based devices, but is significantly more expensive per-unit. We compare the efficacy, safety and total cost associated with the use of the MANTA™ and ProGlide® VCDs.

Methods

This retrospective study included all consecutive patients who underwent transfemoral (TF) TAVI between November 2017-June 2018. The primary endpoints were primary access site-related VARC-2 vascular complications, VARC-2 bleeding and the overall per-patient cost incorporating treatment for complications or use of additional VCDs.

Results

A total of 136 patients were included in this study; 86 in the ProGlide® group and 50 in the MANTA™ group. Baseline characteristics of the two groups were well-matched. Three patients in the ProGlide® group required surgical repair compared to none in the MANTA™ group. However, no significant differences were observed with respect to overall primary access site-related VARC-2 vascular complications (10.5% *vs.* 10%; p=0.93) or VARC-2 bleeding (9.3% *vs.* 4.0%; p=0.25). There was no significant difference in the mean cost per patient when taking into consideration the use of additional VCDs and treatments for vascular complications (£568.79 *vs.* £599.95; p=0.90).

Conclusion

The use of the MANTA™ VCD following TF TAVI is cost-neutral compared to ProGlide® VCDs, whilst being associated with no increase in VARC-2 vascular or bleeding complications.

Keywords

Transcatheter valve interventions; Vascular complications; Vascular closure devices (VCD).

INTRODUCTION

Improvements in device technology and increasing procedural familiarity have allowed for an expansion in the use of transcatheter aortic valve intervention (TAVI). It is advocated by the European Society of Cardiology (ESC) as a viable alternative to surgical aortic valve replacement (SAVR) for selected patients at intermediate surgical risk.[1] Furthermore, recent trials have shown promising results with the use of transfemoral (TF)-TAVI in low surgical risk cohorts.[2,3] The ever-broadening indications for TAVI necessitate a clearer understanding of the risks and complications associated with the procedure. Access site vascular complications remain relatively frequent following TF-TAVI, with a reported incidence of between 4% and 19%.[4] Notably, these complications are associated with significant morbidity as well as increased mortality.[5] Suture-based vascular closure devices (VCD) such as ProGlide® (Abbott Vascular Inc., Santa Clara, CA, USA) are widely used in order to achieve rapid haemostasis following TF-TAVI,

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and have been demonstrated to reduce the rate of vascular complications.[4] However, failure to achieve adequate haemostasis following their use occurs in 4-9% of cases, and can require vascular surgical intervention.[6]

The MANTA™ (Essential Medical Inc., Malvern, PA, USA) is a relatively novel, collagen plug-based VCD which can be used as an alternative to traditional suture-based devices. Previous studies have demonstrated encouraging results, with vascular complication rates equivalent-to or lower-than ProGlide following TF-TAVI7-9. It has also been shown to reduce the need for additional VCDs in order to achieve haemostasis.[7] However, one of the barriers to widespread use of the MANTA™ device is its expense relative to suture-based VCDs; the cost of a MANTA™ device is approximately 5-times the cost of a single ProGlide. This study aims to compare not only the efficacy and safety of ProGlide® and MANTA™ VCDs following TF-TAVI, but also the total cost associated with the use of both devices, when taking into consideration the requirement for additional VCDs and/or treatment of complications.

MATERIALS AND METHODS

This was a retrospective, cohort study undertaken at Leeds Teaching Hospitals NHS Trust (LTHT), a tertiary referral centre for cardiology and cardiac surgery in the United Kingdom. It was designed and reported using the STROBE guidelines.[8]

Participants

All consecutive patients who underwent TAVI between November 2017 and June 2018 were screened for inclusion in the study. The timeframe was selected since it incorporated the first 50 MANTA™ VCD cases at our institute. The inclusion criteria were TF-TA™VI with ProGlide or MANTA™ VCDs. Patients who underwent non-TF-TAVI or required planned femoral surgical cut-down were excluded.

Procedures

The decision to treat patients with TF TAVI was made on a case-by-case basis by the Heart Team following analysis of computerised tomography (CT) scans to ensure adequate vascular access. All procedures were carried out under conscious sedation or general anaesthesia (GA). Vascular access was gained under either fluoroscopic or ultrasound guidance. Unfractionated heparin (UFH) was used in all procedures, with a target activated clotting time (ACT) of >250 seconds. Patients were pre-loaded with 300 mg Aspirin prior to TAVI and maintained on 75 mg once daily thereafter.

For patients in the ProGlide group, 2 ProGlide VCDs were deployed at the beginning of the procedure into the common femoral artery (pre-closure) at the 2 o'clock and 10 o'clock positions. If a third ProGlide VCD was needed, this was deployed at the 12 o'clock position. Additional ProGlide VCDs were deployed at the end of the procedure if required for satisfactory haemostasis (post-closure). The MANTA™ VCD comes in two sizes (14-F and 18-F) and can close arteriotomies of upto 22-F. It comprises a resorbable polymer intra-arterial toggle connected to an extra-arterial hemostatic bovine collagen pad by a non-resorbable polyester suture, and secured with a stainless-steel suture lock. Deployment depth was ascertained at the beginning of the procedure by use of a graduated 8-F puncture dilator. Following completion of the TAVI, the procedural sheath was exchanged for the MANTA™-sheath and the closure unit inserted and withdrawn up to the predetermined deployment level. The toggle was released, assembly component withdrawn, and collagen pad secured onto the outer arterial wall by the stainless-steel lock.

In all cases, haemostasis was assessed *via* use of digital subtraction angiography (DSA). In the ProGlide group, protamine was administered at the discretion of the operator if DSA demonstrated contrast extravasation. For the MANTA™ group, protamine administration was required for all patients.

Variable and Data Sources

The institutional TAVI database was used to identify all patients who underwent TF-TAVI. Once patients had been identified, all clinical and outcome data was retrieved from electronic patient records. Data included patient demographics (age, sex), comorbidities, procedural information (date of TAVI, VCDs used, complications), and outcomes (post-procedure complications, blood transfusions, length of hospital stay, mortality). The cost of devices was obtained from the local procurement team, whilst estimated costs of additional treatments were obtained from our institute's patient-level information and costing systems (PLICS).

Endpoints

The primary endpoints were:

- Primary access site-related Valve Academic Research Consortium (VARC)-2 vascular complications.
- Primary access site-related VARC-2 bleeding complications.
- Overall per-patient cost associated with the use of VCDs, incorporating treatments for complications or use of additional VCDs.

The secondary endpoints were:

- Requirement for primary access site endovascular intervention (excluding balloon angioplasty)
    - Requirement for primary access site surgery
    - Length of hospital stay post-TAVI
    - All-cause 30-day mortality

Statistical Analysis

Statistical analysis was undertaken using Microsoft Excel for Mac (version 15.4). Continuous variables are presented as mean +/- standard deviation and were compared using 2-tailed student's *t*-test. Categorical variables are presented as counts and percentages and were compared using the chi-squared test. *p*-values of less than 0.05 were deemed to be of statistical significance.

Ethics

Institutional approval was sought from the Research and Development Department, on the basis of this study constituting a service evaluation, and therefore not requiring patient consent.

RESULTS

A total of 136 patients were included in this study; 86 in the ProGlide group and 50 in the MANTA™ group. All patients were followed up for 30-days. Baseline characteristics of the two groups were well matched with no significant differences in age, male gender, body mass index (BMI), smoking history, prior myocardial infarction (MI) or percutaneous coronary intervention (PCI), presence of diabetes mellitus, pulmonary disease, peripheral vascular disease, NYHA ≥3 symptoms, pre-procedural haemoglobin, creatinine, anticoagulation or procedural urgency. The only significant difference noted was a higher preponderance in the ProGlide group for history of prior stroke or transient ischaemic attack (Table 1).

No significant differences were noted with respect to the diameter or the extent of calcification of the common femoral artery (CFA) at the site of puncture based on pre-TAVI CT analysis. The mean CFA diameters were 8.1 mm in the ProGlide group and 8.4 mm in the MANTA™ group (p=0.23). The level of CFA calcification was categorised into none, mild, moderate or severe and there were no proportional differences noted between the two groups (Table 2).

Vascular access was predominantly gained under fluoroscopic guidance in both groups (90.7% *vs.* 88.0%; p=0.62) and there were no significant differences in the sheath sizes used (Table 2). In the ProGlide group, a mean of 2.3 ProGlide VCDs (2.1 pre-closure and 0.2 post-closure) and 0.3 Angioseal VCDs were used per patient. In the MANTA™ group, a 1 MANTA™ VCD was used for each patient and no additional VCDs were required (Table 2).

Primary Endpoints

No significant differences were observed between the ProGlide and MANTA™ groups with respect to primary access site-related VARC-2 vascular complications (10.5% *vs.* 10%; p=0.93. See Table 3 and Figure 1a). However, whilst all of the vascular complications in the MANTA™ group were classified as minor, 3 (3.5%) in the ProGlide group were classified as major since they required unplanned surgical intervention and blood transfusion. Similarly, no significant differences were observed with respect to primary access site-related VARC-2 bleeding (9.3% *vs.* 4.0%; p=0.25. See Table 3 and Figure 1b). Once again, all of the bleeding in the MANTA™ group was classified as minor, whilst 3 (3.5%) in the ProGlide group were classified as major since they required unplanned surgical intervention and blood transfusion.

No significant difference was observed between the two groups with respect to mean cost per-patient (p=0.90 see Figures 1, 2). When taking into account the use of additional Angioseal VCDs (25 in total), administration of protamine (26), and the

Table 1. *Baseline Characteristics of the Study Population*

Baseline Characteristics	ProGlide n=86	MANTA n=50	*p* value
Age, years	79.1+/-8.0	81.5+/-6.8	0.07
Male gender (%)	49 (57.0)	28 (56.0)	0.91
BMI, kg/m^2	28.2+/-4.6	28.5+/-6.0	0.82
Diabetes mellitus (%)	26 (30.2)	12 (24.0)	0.43
Smoking history (%)	50 (58.1)	20 (40.0)	0.06
Pulmonary disease (%)	19 (22.1)	8 (16.0)	0.39
Pulmonary disease (%)	19 (22.1)	8 (16.0)	0.39
Peripheral vascular disease (%)	4 (4.7)	1 (2.0)	0.43
Prior CVA (%)	12 (14.0)	1 (2.0)	0.02
Prior MI (%)	11 (12.8)	3 (6)	0.21
Prior PCI (%)	16 (18.6)	4 (8.0)	0.09
NYHA ≥3 (%)	56 (65.1)	31 (62.0)	0.72
Pre-procedure creatinine, µmol/L	107.1+/-69.0	96.1+/-37.9	0.25
Pre-procedure Hb, g/L	121.8+/-16.1	122.4+/-16.0	0.83
Pre-procedure oral anticoagulation (%)	27 (31.4)	15 (30)	0.87
DOAC (%)	24 (27.9)	13 (26)	0.81
Warfarin (%)	3 (3.5)	2 (4)	0.88
Urgent or emergency TAVI (%)	8 (9.3)	6 (12.0)	0.59

BMI: body mass index; CVA: cerebrovascular attack; MI: myocardial infarction; PCI: percutaneous coronary intervention; NYHA: New York Heart Association; DOAC: direct oral anticoagulant; TAVI: transcatheter aortic valve implantation.

Table 2. *Vascular Access Related Procedural Data*

Vascular Access Related Procedural Data	ProGlide n=86	MANTA n=50	*p* value
Common femoral artery diameter (mm)	8.11+/-1.39	8.40+/-1.34	0.23
No common femoral artery calcification (%)	24 (27.9)	15 (30.0)	0.79
Mild common femoral artery calcification (%)	41 (48.2)	24 (48.0)	0.97
Moderate common femoral artery calcification (%)	16 (18.8)	9 (18.0)	0.93
Severe common femoral artery calcification (%)	5 (5.9)	2 (4.0)	0.64
Ultrasound guided puncture (%)	8 (9.3)	6 (12.0)	0.62
14F sheath (%)	22 (25.6)	8 (16.0)	0.19
16F sheath (%)	40 (46.5)	29 (58.0)	0.20
18F sheath (%)	24 (27.9)	13 (26.0)	0.81
Peak activated clotting time (sec)	252.5+/-39.5	244.3+/-38.6	0.25
ProGlides used for pre-closure (mean per patient)	179 (2.1)	0 (0)	-
ProGlides used for post closure (mean per patient)	18 (0.21)	0 (0)	-
Total number of ProGlides used (mean per patient)	197 (2.3)	0 (0)	-
MANTA used (mean per patient)	0 (0)	50 (1)	-
Angioseals used (mean per patient)	25 (0.3)	0 (0)	-

Table 3. *Procedural Outcome Data*

Procedural Outcomes	ProGlide n=86	MANTA n=50	*p* value
Contrast extravasation on initial angiogram (%)	35 (40.7)	23 (46.0)	0.55
Requirement for balloon tamponade (%)	20 (23.3)	3 (6.0)	0.01
VARC-2 VCD failure (%)	3 (3.5)	0 (0)	-
Primary access site-related VARC-2 vascular complications (%)	9 (10.5)	5 (10.0)	0.93
Minor (%)	6 (7.0)	5 (10.0)	0.53
Major (%)	3 (3.5)	0 (0)	-
Non-primary access site related VARC-2 vascular complications (%)	4 (4.7)	2 (4)	0.86
Minor (%)	3 (3.5)	2 (4)	0.88
Major (%)	1 (1.2)	0 (0)	-
Primary access site-related VARC-2 bleeding (%)	8 (9.3)	2 (4.0)	0.25
Minor (%)	5 (5.8)	2 (4.0)	0.64
Major or life-threatening (%)	3 (3.5)	0 (0)	-
All VARC-2 bleeding (%)	12 (14.0)	2 (4)	0.66
Minor (%)	3 (3.5)	2 (4)	0.88
Major or life-threatening (%)	9 (9.3)	0 (0)	-
Requirement for primary access site endovascular intervention (%)	0 (0)	0 (0)	-
Requirement for primary access site vascular surgery (%)	3 (3.5)	0 (0)	-
Red blood cell transfusion (%)	7 (8.1)	0 (0)	-
Hb drop, g/L	18.4+/-9.1	16.0+/-10.8	0.19
Length of hospital stay post-procedure, days	3.2+/-3.5	2.6+/-2.6	0.27
30-day mortality (%)	0 (0)	0 (0)	-

VARC:Valve Academic Research Consortium;VCD: vascular closure device

Table 4. *Cost of VCDs and Supplementary Interventions for ProGlide Group*

VCDs and Supplementary Interventions for ProGlide Group (n=86)	Total Number	Cost per Unit (£)	Total Cost (£)
ProGlide	197	115.00	22655.00
Angioseal	25	101.00	2500.00
Protamine	26	49.55	1288.30
Red blood cell transfusion	7	128.99	902.93
Surgical repair	3	7190.00	21570.00
Combined cost			48916.23
Mean cost per patient			568.79

Table 5. *Cost of VCDs and Supplementary Interventions for MANTA Group*

VCDs and Supplementary Interventions for MANTA group (n=50)	Total Number	Cost per Unit (£)	Total Cost (£)
MANTA	50	550.00	27500.00
Angioseal	0	101.00	0
Protamine	50	49.55	2477.50
Red blood cell transfusion	0	128.99	0
Surgical repair	0	7190.00	0
Combined cost			29977.50
Mean cost per patient			599.55

requirement for red blood cell transfusions[7] and surgical repair,[3] the mean cost per patient in the ProGlide group was £568.79 (see Table 4, Figure 2). In the MANTA™ group, when accounting for the cost of the VCD and administration of protamine in all cases, the mean cost per patient was £599.55 (Table 5, Figure 2).

Secondary Endpoints

None of the patients in either group required primary access site endovascular intervention (excluding balloon angioplasty). Two patients in the ProGlide group required endovascular intervention to the contralateral femoral artery (thrombin injection for psedoaneurysm and covered stent for injury to superficial femoral artery). As mentioned above, 3 patients in the ProGlide group required primary access site surgical repair due to common femoral artery injury in contrast to none in the MANTA™ group. There was no significant difference observed with respect to duration of hospital stay post-TAVI (3.2+/-3.5 *vs.* 2.6+/-2.6 days; p=0.27. See Table 3) and there was no 30-day mortality in either group.

Additional Endpoints

The overall rate of VARC-2 vascular complications across all patients was 14.7% (20/136), whilst the overall rate of VARC-2 bleeding was 10.3% (14/136). There was no significant difference between the two groups with respect to peak ACT. However, a significantly greater proportion of patients in the ProGlide group required balloon tamponade following DSA in order to achieve haemostasis (23.3% *vs.* 6.0%; p=0.01). Seven patients in the ProGlide group required post-procedure transfusion of red blood cells compared to none in the MANTA™ group. However, there was no significant difference in mean drop in haemoglobin post-procedure (18.4+/-9.1 *vs.* 16.0+/-10.8 g/L; p=0.19).

DISCUSSION

The MANTA™ VCD is an alternative to traditional suture-based VCDs such as ProGlide for achieving vascular closure and haemostasis following TF-TAVI. A multi-centre prospective study of the MANTA™ VCD demonstrated good efficacy and low complication rates,[9] and our group has described its use as a rescue for failed ProGlide pre-closure in a case which would otherwise have warranted surgical intervention.[10] Furthermore, a number of previously published retrospective studies have demonstrated encouraging results when comparing vascular and bleeding complications.[7,11,12] However, the significantly higher cost of the MANTA™

Figure 1. *A. Graph Comparing the Proportion of Patients with Primary Access Site-Related VARC-2 Vascular Complications in ProGlide and MANTA Groups. B. Graph Comparing the Proportion of Patients with Primary Access Site-Related VARC-2 b Feeding in ProGlide and MANTA Groups. C. Graph Comparing the Mean Per-Patient Cost of Achieving Haemostasis in ProGlide and MANTA Groups.*

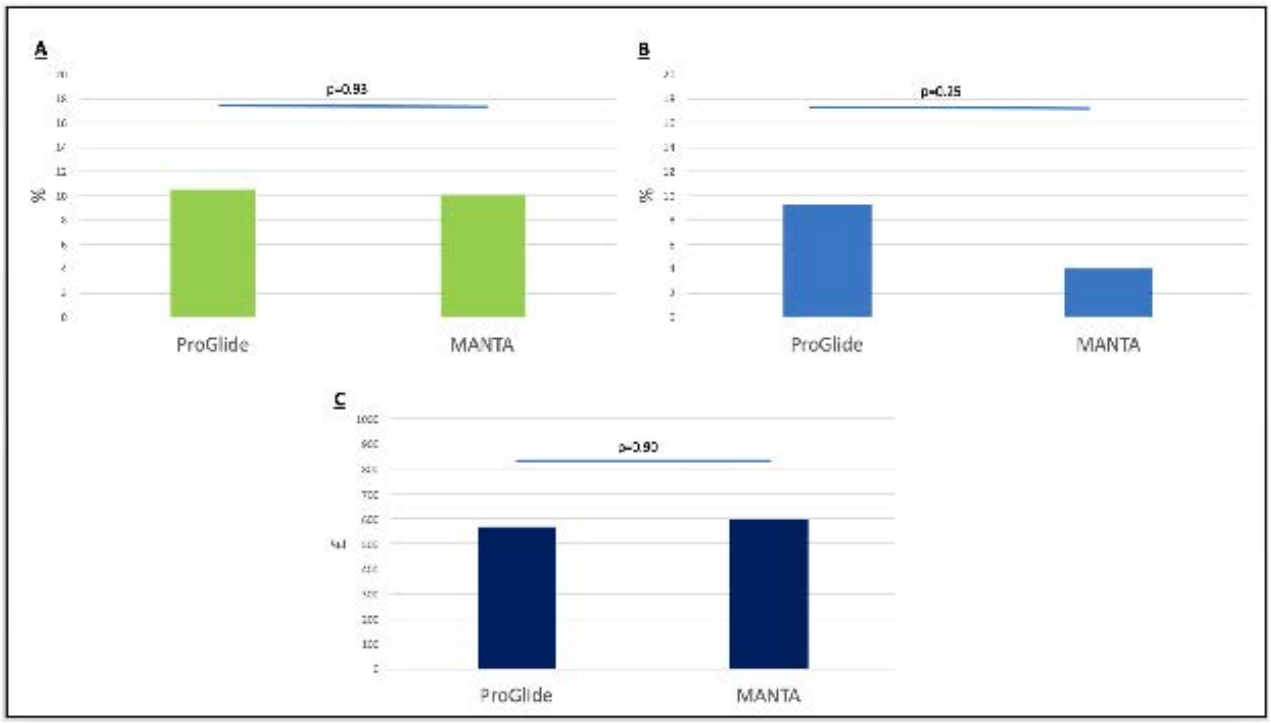
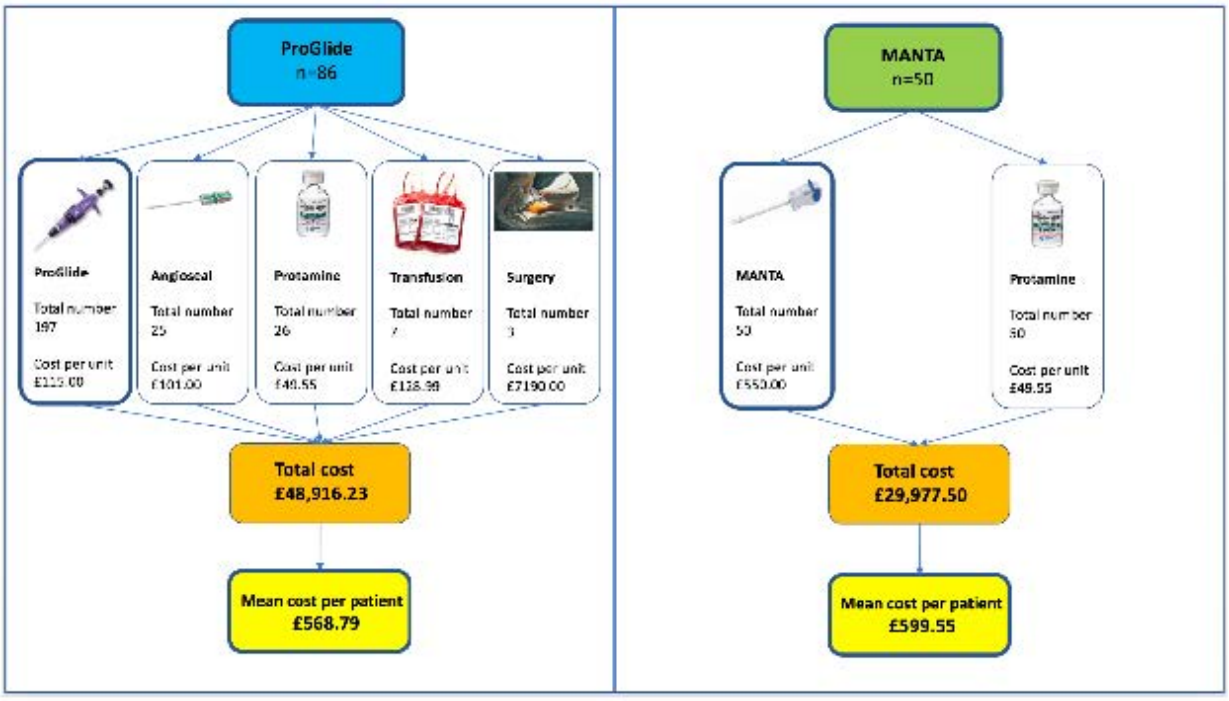


Figure 2. *A Pictorial Comparison of the Mean Cost per Patient in ProGlide and MANTA Groups*



VCD has been a concern, and has limited its use in many centres. This single-centre, retrospective study explores in greater detail the cost comparison between ProGlide and MANTA™ VCDs, as well as providing additional data regarding vascular and bleeding complication rates.

This study of 136 patients shows a 14.7% overall rate of VARC-2 vascular complications. This is consistent with other studies[7,9,11,12] but highlights that vascular injury remains relatively frequent following TF TAVI. Our data demonstrate no significant differences between ProGlide and MANTA™ VCDs with respect to overall VARC-2 vascular (10.5% *vs.* 10.0%; p=0.93) or bleeding (9.3% *vs.* 4.0%; p=0.25) complications at the primary access site. These findings are consistent with that of a similarly designed study published by Biancari et al.[7] However, when analysing the complications in more detail it is notable that three of the patients in the ProGlide group went on to have open vascular surgical repair of the primary access site compared to none in the MANTA™ group. As such, when assessing major VARC-2 vascular or bleeding complications only, there was a notable discrepancy between the two groups. This potentially corroborates the findings of Moriyama et al,[12] where use of MANTA™ was associated with a lower rate of vascular and bleeding complications, especially for major bleeding.[13]

The most novel and significant finding from the present study is that of cost neutrality between ProGlide and MANTA™ groups. Whilst a single MANTA™ VCD is approximately 5 times more expensive than a single ProGlide VCD (£550.00 vs. £115.00), the gap is narrowed to the point of being non-statistically significant when taking into consideration the mean per-patient cost due to use of additional VCDs and treatments for complications (£599.55 *vs.* £568.79).

This study has a number of limitations which need to borne in mind when appraising the results. Chief among these is the fact that it was non-randomised, which means that we cannot rule out selection bias within the study population. The decision to use ProGlide or MANTA™ VCDs was made at the discretion of the operator following analysis of a CT scan showing the extent of disease of the ileo-femoral vasculature. Whilst the patient groups appear well-matched with respect to baseline (demographics and comorbidities) and procedural (method of vascular access, sheath size, peak ACT) characteristics, it is feasible that ProGlide may have been selected in cases with more complex peripheral vascular anatomy due to greater operator familiarity. Furthermore, the cases included in this study pre-date the widespread uptake of ultrasound guided vascular access in our institute. Ultrasound was used in only 10.3% of cases in this study, whereas its use is now near-universal. The use of ultrasound allows for real-time assessment of vessel wall health, including calcification, allowing the operator to select the optimal puncture site. This is particularly pertinent to the use of ProGlide VCDs, since calcification and atheromatous disease can prevent suture-based VCDs from drawing together the edges of an arteriotomy. In contrast, the MANTA™ VCD is less reliant on the quality of the artery. Taking all of the above into account, it could be argued that the conditions of the study were more advantageous towards the MANTA™ VCD. However, as a counterpoint, it should be noted that this study involved the first 50 cases of MANTA™ usage post-TAVI at our institute and therefore incorporated the operator learning curve that is inherent to the use of all novel devices.

CONCLUSION

This study demonstrates that use of the MANTA™ VCD following TF TAVI is associated with no increase in primary access site-related VARC-2 vascular or bleeding complications relative to ProGlide VCDs, whilst also being cost-neutral when overall per-patient expense is considered. Whilst further studies, including randomised controlled trials (RCTs), are warranted in order to explore this in more detail, current evidence suggests the MANTA™ VCD to be a clinically and economically viable alternative to traditional suture-based VCDs.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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Systematic Review

Cardiovascular Health and Healthcare Use of United States-Born and African-Born Blacks: A Review

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ABSTRACT

Introduction

Cardiovascular disease (CVD) is the leading cause of death globally, with Blacks in the United States (U.S.) disproportionately affected. Healthcare access and utilization have been reported as risk factors for poorer cardiovascular health among several U.S. populations.

Aims and Objectives

The purpose of this systematic literature review was to examine the results of existing studies reporting on cardiovascular health and healthcare utilization by African-born compared to U. S. -born Blacks.

Methods

A systematic literature review was conducted using keywords and medical subject headings (MESHs) in the PUBMED, Web of Science and CINAHL electronic databases. Exclusion and inclusion criteria determined articles to be reviewed for eligibility and methodological soundness. A pooled analysis was performed on all studies.

Results

Only seven studies met inclusion criteria. Four compared U. S. -born with African-born Blacks residing in the United States, while three compared U. S. -born Blacks with Blacks residing elsewhere. None of the studies examined the associations between healthcare utilization and cardiovascular health for these populations.

Conclusion

The results of this review indicate a need to examine the impact of healthcare utilization for increasing awareness, prevention and treatment of CVD in Blacks who reside in the United States regardless of their nativity.

Keywords

Cardiovascular health; African-born Blacks; U.S-born blacks; Healthcare utilization.

Abbreviations

CVD: Cardiovascular disease; US: United States; MESHs: Medical subject headings; sBP: Systolic blood pressure; dBP: Diastolic blood pressure; BMI: Body mass index; BP: Blood pressure.

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death globally.[1] The prevalence of hypertension, a known risk factor for developing CVD, is the highest in the world for U. S. -born Blacks.[2] The American Heart Association reports that "*little has changed since 2005 when notable disparities were observed in prevalence, disease management and outcomes*" in CVD rates for Black populations in the United States.[2]

To date, researchers do not have a definitive explanation for why Blacks in the United States are more predisposed to worse cardiovascular outcomes than their White counterparts.[3] Major differences in cardiovascular outcomes have also been observed among people of African-born origin when compared to U. S. -born Blacks. Specifically, traditional African populations show a low prevalence of cardiovascular risk factors such as hypertension, high cholesterol, diabetes mellitus, obesity, physical activity, smok-

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ing status, and diet.[4,5] Forrester[6] states that genetics seem to be a likely factor to explain this scenario; however, no causative gene has been identified and researchers have been unable to support the proposal that populations of African origin are genetically predisposed to developing CVD. Hence, it remains instructive to look at non-genetic factors that might account for the CVD disparities experienced by African-origin Blacks residing in the United States. This critical literature review appraised existing studies that examined cardiovascular health in African-born Blacks compared to U. S. -born Blacks, as well as associations between healthcare utilization and cardiovascular health for these populations.

BACKGROUND

Africans now make up 39% of the overall foreign-born Black population in the United States (up from 24% in 2000), and their population more than doubled between 2000 and 2016[7] making them the fastest growing group of foreign-born Blacks in the United States.[8] It is challenging to determine the contribution of cultural, social, behavioral and lifestyle contributions to the cardiovascular health and other health outcomes of U. S. -born *versus* African-born Blacks because most studies treat Blacks in the United States as a monolithic group.[9-11]

Results of research by Venters et al[12] suggest that African-born Blacks experience better health outcomes, including a lower prevalence of chronic diseases such as hypertension because of the "*healthy immigrant effect*." Their research suggests that immigrants are likely healthier than their host counterparts due to migrant selectivity during the immigration process. Despite this claim, studies in other immigrant groups show that through acculturation, the health of immigrants declines as they adopt the lifestyle practices and health behaviors of their host society.[13,14]

It is unclear whether the acculturation effect is impacted by region of birth or if it is the result of other factors. For example, Golub et al[15] showed that African refugees from Liberia had the highest-levels of hypertension after resettlement compared to all other refugee immigrants. In comparison, those from other African countries (Burkina Faso, Burundi, Chad, Congo, Eritrea, Ethiopia, Nigeria, Sierra Leone, Togo) had the lowest-levels of hypertension. Within a year of resettlement in the United States, immigrants from other African countries had the lowest levels of diabetes while those from Somalia had the highest-levels of diabetes. There were several confounding factors observed among resettled refugee adults with longer length of stay in the United States, including increased odds of Type 2 diabetes and hypertension, irrespective of country of origin.

Recent studies of Africans residing in the United States show similar or higher rates of CVD risk factors. Njeruand colleagues[16] found that Somali immigrant patients had a significantly higher prevalence of diabetes, pre-diabetes and obesity than did non-Somali patients. Measuring CVD risk factors in a population of Nigerians and Ghanaians in the United States, Commodore-Mensah et al[17] found a prevalence of hypertension at 40%, diabetes at 16%, and of being overweight or obesity at 88%. Overall, 80% of those sampled were reported to have at least two CVD risk factors. These statistics are alarming given the fact that 79% of those in the study were employed, 60% had a college degree or higher, and 48% were uninsured. However, due to a lack of population frame of West African immigrants in the United States, we are unable to compare these results to the general population.

Derose et al[18] report that educational attainment, type of occupation, and earnings directly and indirectly influence immigrants' access to health care resources. This could explain why there was such a high prevalence of CVD risk among the immigrant population in the Commodore-Mensah et al[17] study described above. Legal status is another vulnerability risk factor to accessing healthcare even though 77% of immigrants reported that they were permanent residents of the United States. It is likely that these high-risk rates are because of acculturation since 67% of those sampled lived in the United States for 10-years or more. Such findings challenge the argumentfor the healthy immigrant effect among African-born Blacks.[19]

There is a need for researchers to delineate health risk and outcomes data on African-born Blacks from those for U.S.-born Blacks. With such knowledge, more effective programs might be developed that could reduce the disparities between Blacks and Whites residing in the United States. Concerted prevention and treatment efforts addressing the cultural differences among Black subgroups could be more effective than those addressing the group as a monolith.

Having health insurance has also been shown to reduce the risk of CVD. For example, a study of West African immigrants in the United States found an association between women having health insurance and a reduced risk of CVD.[20] African immigrants as a whole were the least likely to be insured and were also less likely to report having seen a doctor in the past year. The authors also reported African immigrants had the highest prevalence of hypertension and diabetes.

Despite the findings listed above, no study to date hascomparatively analyzed the association between healthcare utilization and cardiovascular health among African-born and U.S.-born Blacks. Therefore, this critical literature review sought out existing studies that examined cardiovascular health in African-born Blacks compared to U.S.-born Blacks and any reportson the associations between healthcare utilization for those groups and cardiovascular health outcomes.

METHODS

This study protocol was reviewed and granted exempt status by the Rutgers University IRB on May 19, 2020 (#Pro2020000823). The strategy for this systematic literature review followed PRISMA guidelines.[21] One hundred two (102) studies were systematically examined related to the cardiovascular health of African-born and U. S. -born Blacks to assess whether healthcare utilization was examined as a predictor for cardiovascular health. Searches were undertaken using keywords and medical subject headings (MESHs) in the PUBMED, Web of Science and CINAHL electronic databases. Subsequently, the reference list of relevant identified articles was

examined to retrieve other studies that were not included in either of the three databases. Keywords and MESHs, truncated and exploded to capture as many articles as possible, were used in the development of search strategies, including: African immigrants, Sub-Saharan African born, Africa born Blacks, African American, U.S. born Black, Black Americans, Blacks, healthcare utilization, healthcare use, healthcare accessibility, health access, access to health care, realized access, cardiovascular disease, cardiovascular health. The exact syntax of the search terms is available from the first author upon request. In order to not limit the search, articles were selected from 1900 through 2019, however, they were limited to English language journals and adult-only populations.

Study Selection and Data Extraction

A 3-stage screening process was conducted, starting with a title review, followed by an abstract review, and ending with a full-text article review (Figure 1). Inclusion criteria were: studies comparing U. S. -born with African-born Blacks; studies of cardiovascular health factors (i.e., hypertension, obesity, physical activity, smoking, diabetes mellitus, high cholesterol, nutrition); studies of access to healthcare or healthcare utilization (i.e., insurance status, usual source of care, having a regular provider). Exclusion criteria were studies of mortality or using qualitative data only.

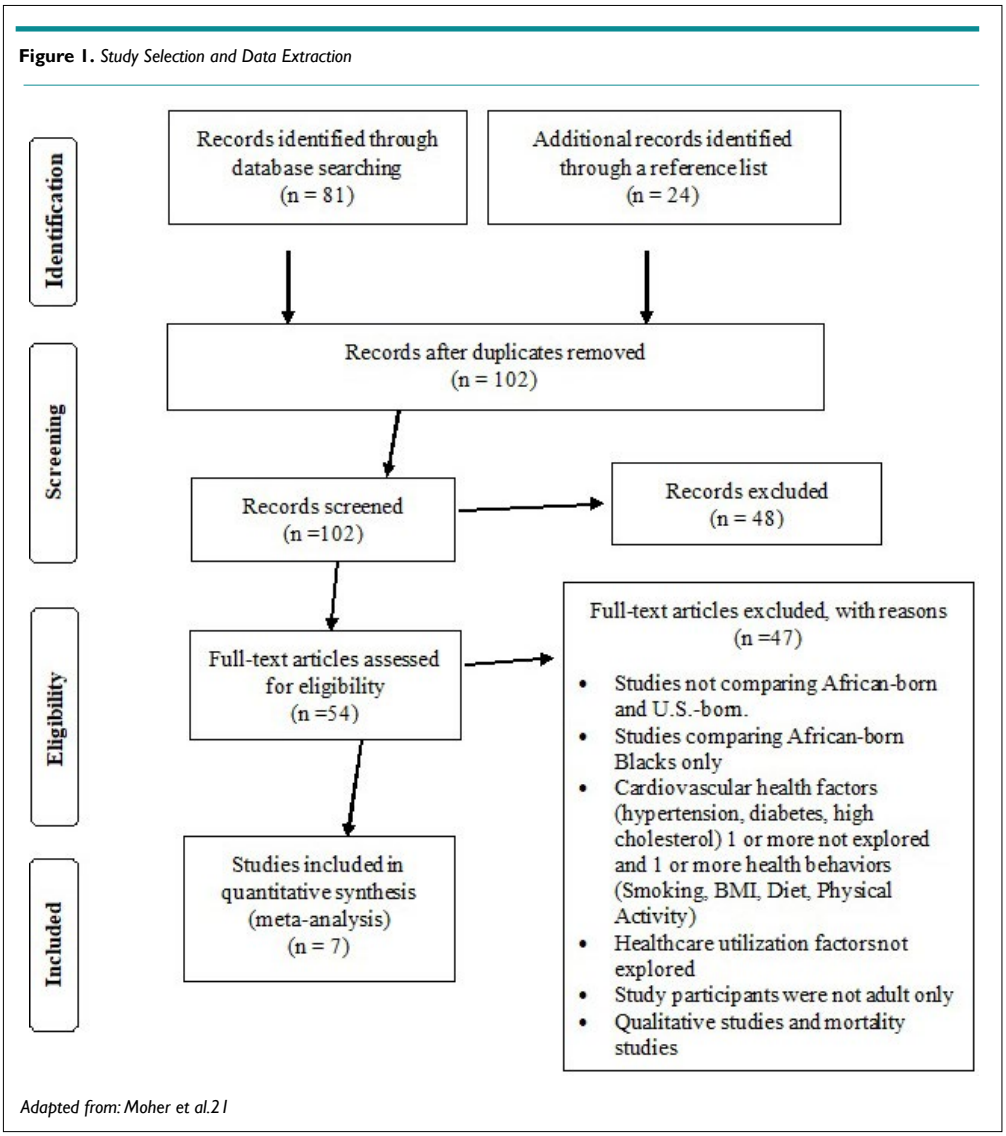
In the title review phase, 102 articles were screened and 48 articles were excluded, yielding 54 relevant articles. Articles were excluded that did not indicate if foreign-born Blacks in the study originated from Africa. Abstracts of the articles were examined for keywords; however, to avoid losing any relevant articles all 54 articles were reviewed fully. The full texts of the articles were then thoroughly examined for eligibility based on the inclusion criteria and methodological soundness. A pooled analysis was performed on all studies.

RESULTS

Figure 1 shows the systematic literature review process with the resulting number of articles remaining at each step. Seven (7) studies were eventually included in this review, as one eligible study was dropped as the participants were identical to those in one of the other studies selected.[22]

Four (4) of the studies compared African-born Blacks

Figure 1. *Study Selection and Data Extraction*



Adapted from: Moher et al.21

residing in the United States with U. S. -born Blacks only. Three (3) of the studies compared Africans living in Africa to U. S. -born Blacks residing in the United States. All of the studies examined systolic blood pressure (sBP), diastolic blood pressure (dBP), and body mass index (BMI); five (5) studied diabetes (fasting glucose); three (3) studied total cholesterol; three (3) studied physical activity and smoking, and one (1) examined subjects' fruit and fiber intake. Only one of the seven studies looked at access to healthcare (insurance), and none measured healthcare utilization (Table 1).

Black Africans Living in the United States *vs.* U.S.-Born Blacks

In the four studies examining Africans residing in the United States, the majority had lived in the country for 10-years or more (over 80% in one study). Sample sizes in the studies ranged from 95 to 214 individuals. Three of the studies examined men only[23-25] while the study by Hyman et al[26] examined men and women. Two of the studies used physical measurements that were taken after a 12-hour fast using a standard epidemiological protocol of rest in a seated position for a period, then taking three separate blood pressure measurements with two-minutes separating each reading. The first reading was omitted and the last two were averaged to obtain the sBP and dBP.[25,26]

Table 2 shows a detailed analysis of the measurements which were available for all four studies by sex. Africans were not delineated into regions of origin except in the O'Connor et al[23] study. The mean age of participants ranged from 34-years to 45-years. The mean sBP ranged from 121.8 to 130 mmHg; the mean dBP ranged from 71 to 82.7 mmHg; and the mean fasting glucose ranged from 86 to 103.2 mg/dL. The mean total cholesterol levels ranged from 153 to 200.9 mg/dL. Lastly, the mean BMI levels ranged from 26.3 to 31.3. Ukegbu et al[27] did not report total cholesterol levels.

Physical activity was reported for those who indicated exercising moderately or more (i.e. 30-minutes or more), for at least three times a week.[23,24,26] The range of participants who exercised moderately was from 17% to 72%; Ukegbu and et al[25] did not report physical activity levels. Lastly, two studies reported smoking

Table 1. *Description of Selected Studies, by Year of Publication*

Author	Title	Journal	Populations	N	Years in U.S.	Gender	Risk Factors
O'Connor et al[23]	Worse cardiometabolic health in African immigrant men than African American men: reconsideration of the healthy immigrant effect	Circulation	African-born, African American	214	11±9 (0.1-42)	Males	BMI, hypertension, cholesterol, diabetes, physical activity, smoking, insurance
Cooper et al[31]	The prevalence of hypertension in seven populations of West African origin	American Journal of Public Health	West African (Nigeria and Cameroon); Caribbean (Jamaica, St. Lucia, Barbados); U.S.-born Black (metropolitan Chicago)	10,014	-	Both	BMI, hypertension
Hyman et al[26]	Lower hypertension prevalence in first-generation African immigrants compared to US-born African Americans	Ethnicity and Disease	African-born, African American	182	< 5=7% 5-10=3% >10=80%	Both, not de-lineated	BMI, hypertension, cholesterol, diabetes, diet, physical activity
Poston et al[22]	Genetic bottlenecks, perceived racism, and hypertension risk among African Americans and first-generation African immigrants	Journal of Human Hypertension	African-born, African American	185	< 5=7% 5-10=3% >10=80%	Both	BMI, hypertension, cholesterol, diabetes, smoking
Ukegbu et al[25]	Metabolic syndrome does not detect metabolic risk in African men living in the U.S.	Diabetes Care	African-born, African American	95	10±7 (0.2-27)	Males	BMI, hypertension, diabetes, cholesterol
Yu et al[24]	Triglycreide-Based Screening Tests Fail to Recognize Cardiometabolic Disease in African Immigrant and African- American Men	Metabolic Syndrome Related Disorders	African-born, African American	155	10±10	Males	BMI, hypertension, diabetes, smoking, physical activity, cholesterol
Okosun et al[32]	Association of waist circumference with risk of hypertension and type 2 diabetes in Nigerians, Jamaicans, and African- Americans	Diabetes Care	Nigerian, Jamaica, African- American	5,042	-	Both	BMI, hypertension, diabetes
Cooper et al[33]	Elevated hypertension risk for African-origin populations in biracial societies: Modeling the Epidemiologic Transition Study	Journal of Hypertension	African American (Chicago), Jamaican (Kingston), Rural Ghanian, South African (Cape Town), Seychelles	2500	-	Both	BMI, hypertension

*Note: * All studies were cross-sectional in design*

Table 2. *Subjects and cardiovascular risk factors among African and U.S-born Blacks residing in the United States, by sex and year of publication*

Author	Origin of Population	N (%)	Mean Age±SD	sBP*±SD	dBP**±SD	Fasting glucose ±SD	Total	BMI***±SD	Physical Activity %	Smoker %
Male Subjects										
Hyman et al[26]	Africa	19 (59.3)	43±7.2	126.6±20.1	82.0±12.7	99.8±41.3	197.3±46.9	26.3±3.2	72	-
	U.S.	13 (40.6)	43±7.1	129.5±15.5	82.7±9.9	95.3±11.3	191.0±55.5	31.1±5.7	50	-
Ukegbu et al[25]	Africa	39 (41)	38±5	130±14	79±10	94±9	-	28±4.3	-	-
	U.S.	56 (59)	38±6	121±13	71±9	89±8	-	30.5±6.4	-	-
Yu et al[24]	Africa	80 (52)	36±9	126±13	76±9	92±8	158±31	27.3±3.8	27	6
	U.S.	75 (48)	35±8	121±12	71±10	88±8	174±41	29.8±6.2	35	21
	West Africa	68 (32)	40±10	126±14	76±10	92±14	166±33	27.2±3.8	32	8
	Central Africa	41 (19)	35±8	125±13	74±10	92±9	153±30	28.0±4.3	17	0
	East Africa	29 (13.5)	35±7	122±11	74±9	92±7	161±31	26.9±3.4	31	12
	U.S.	76 (35.5)	34±8	121±12	71±9	86±7	175±41	29.3±5.5	49	16
Female Subjects										
Hyman et al[26]	Africa	66 (44)	40±5.8	121.8±15.4	77.6±11.0	91.7±16.9	199.4±59.2	28.9±3.9	30	-
	U.S.	84 (56)	44.9±9.0	124.8±17.0	82.7±9.9	103.2±42.7	200.9±45.9	31.3±5.7	50	-

*Notes: *Systolic blood pressure; **Diastolic blood pressure; ***Body mass index*

Table 3. *Results of Pooled Analysis for Cardiovascular Risk Factors among African Born and U.S.-born Black Males Residing in the United States*

Region	N (%)	Mean Age±SD	sBP*±SD	dBP**±SD	Fasting glucose±SD	Total cholesterol±SD	BMI***±SD	Physical Activity %	Smoker %
African	276 (56)	37.8±7.7	126±14.2	77±10.1	93.6±14.7	167.1±29†	27.3±3.8	35.8††	6.5††
United States	220 (44)	37.5±7.2	123±13	74±9.5	89.6±8.6	180±46†	30.2±6	45††	18.5††

*Notes: *Systolic blood pressure; **Diastolic blood pressure; ***Body mass index; †Ukegbu et al[25] missing; ††Hyman et al[26] missing*

rates from 0% to 21%.[23,24] African women reported lower-levels on all measurements compared to U.S.-born Black women, indicating a lesser risk of CVD for African born women living in the United States.

Table 3 presents the results of the pooled analysis for males residing in the United States. There were no significant differences in the ages of African men and U. S. -born Blacks who were sampled. African men reported higher sBP and dBP, indicating a higher-risk of hypertension compared to U. S. -born Black men.

African men also reported significantly higher-levels of glucose than did U.S.-born Black men (93.6±14.7 mg/dL compared to 89.6±8.6 mg/dL). U. S. -born Black men however, reported higher cholesterol levels and BMIs, physical activity, and smoking levels. Comparing this pooled analysis of the men with the women studied in Hyman et al's[26] study, the women studied were older, had a higher BMI, were less likely to smoke, and were just as likely to be physically active across both African-born and U.S.-born Blacks.

African-born men were more likely to have elevated risk of hypertension and higher glucose levels than African-born women, while African-born women were significantly more likely to have high cholesterol. U.S.-born Black men were significantly less likely to have higher glucose levels and higher cholesterol than U.S.-born Black women and they had similar elevated risks of hypertension.

Each study reported mean BMI levels of participants. Overweight/obesity is closely linked to hypertension and cardiovascular diseases[27,28] and this connection is reported in several of the studies with high mean BMIs correlating to high blood pressure levels.[23-26] Cholesterol levels were significantly higher in U.S.-born Blacks than in African-born Blacks, for both males and females. An unhealthy diet, lack of physical activity, smoking and obesity were all behavioral risk factors associated with high cholesterol. A review of relevant literature shows a pattern of higher smoking rates and higher prevalence of overweight/obesity and although comparatively higher than among African-born Blacks, U.S-born Blacks reported a relatively low prevalence of physical activity compared to the national sample.[29] Lastly, O'Connor et al[23] found that immigrant African-born Black men were less likely to have health insurance. They concluded that African-born Black men were therefore less likely to visit a primary care provider, and despite self-reporting as healthy, these factors further contribute to the higher prevalence of undiagnosed diabetes.

African Blacks Living Outside the U. S. *vs.* U. S. -Born Blacks

The studies comparing Black Africans remaining in their country

Table 4. *Cross Sectional Studies on Hypertension and BMI of Males by Nativity–Outside vs U.S-born*

Author	Country	N (%)	Mean Age±SD	sBP*±SD	dBP**±SD	BMI***±SD
Cooper et al[31]	Nigeria	1171 (25.5)	-	121.5±19.7	73.3±13.0	21.7±3.6
	Cameroon	1357 (29.6)	-	121.8±15.7	76.1±11.7	24.3±3.3
	Caribbean	1345 (29.4)	-	125.2±18.9	74.7±13.1	24.7±4.1
	United States	708 (15.5)	-	125.3±19.5	73.9±13.4	27.1±5.5
Okosun et al[32]	Nigeria	875 (39)	41.5±12.3	120±19.1	71.6±13.8	22.5±4.4
	Jamaica	510 (23)	46.8±14.2	122.3±21.3	70.0±15.1	23.8±4.2
	United States	844 (38)	45.9±14.1	126.4±8.8	78.4±12.0	26.5±5.0
Cooper et al[33]	Ghana	207 (18)	34.6±6.7	118.9±13.1	68.5±11.4	22.2±2.7
	South Africa	232 (20)	33.7±5.6	129±17.1	79.6±13.2	22.4±4.3
	Jamaica	249 (21)	34±5.9	121.5±12.8	71.2±11.1	23.6±4.5
	Seychelles	230 (20)	36.5±5.1	122.7±14.6	75.0±11.4	26.5±4.9
	United States	243 (21)	35.5±6.2	127.9±14.5	81.0±12.1	29.7±7.6

*Notes: *Systolic blood pressure; **Diastolic blood pressure; ***Body mass index*

Table 5. *Cross Sectional Studies on Hypertension and BMI of Females by Nativity–Outside vs U.S-Born*

Author	Country	N (%)	Mean Age±SD	sBP*±SD	dBP**±SD	BMI***±SD
Cooper et al[31]	Nigeria	1338 (25)	-	119.1±21.8	72.1±12.8	22.6±4.7
	Cameroon	1471 (27)	-	118.9±21.8	73±12.8	25.2±4.5
	Caribbean	1814 (33)	-	122.3±21.3	72.6±13.4	28.2±6.4
	United States	810 (15)	-	122.4±19.6	72.7±11.8	30.8±7.7
Okosun et al[32]	Nigeria	1056 (37.5)	40.0±11.3	116.5±20.5	69.5±14.0	22.9±5.2
	Jamaica	776 (27.5)	45.9±13.2	121.3±21.9	69.3±14.7	28.0±6.5
	United States	983 (35)	44.4±13.3	121.3±21.7	73.2±12.6	29.4±6.9
Cooper et al[33]	Ghana	293 (22)	34.0±6.6	110.5±15.2	66.2±11.48	25.5±5.2
	South Africa	268 (20)	33.1±6.0	118.2±18.6	76.3±11.8	31.9±8.2
	Jamaica	251 (19)	34.7±6.2	115.2±14.7	72.1±11.4	29.5±6.7
	Seychelles	270 (20)	35.8±6.0	110.8±12.8	71.2±9.9	27.6±6.2
	United States	257 (19)	35.0±6.3	117.5±16.1	79.6±13.2	34.1±8.8

*Notes: *Systolic blood pressure; **Diastolic blood pressure; ***Body mass index*

of origin and U.S.-born Blacks provide some interesting results. Richard Cooper was the primary author or co-author of all three studies that examined Black men and women in West Africa, East Africa, South Africa, the Caribbean, and the United States.[30-32] Due to insufficient reporting on some of the measurements, only the results from blood pressure and BMI measurements can be reported here. Systolic and diastolic blood pressure were measured as reported above. Height and weight in light clothing with no shoes and measured on a digital scale were used to calculate BMI.[30-32]

Tables 4 and 5 show the results by region of origin and sex. For African-born Black men, the mean age ranged from 34 to 47-years while for women, it ranged from 30 to 46-years. For men, sBP ranged from 118.9 to 127.9 mmHg while for women, it ranged from 110.5 to 122.6 mm Hg. For men, dBP ranged from 68.5 to 81 mm Hg while for women, it ranged from 66.2 to 79.6 mmHg. For men, BMI ranged from 21.7 to 29.7 kg/m^2 while women ranged from 22.6 to 34.1 kg/m^2. The pooled analysis (Table 6) shows that for both Black men and women, Africans residing in their country of origin were younger, less likely to have an elevated risk of hypertension, and less likely to be overweight and obese than their U.S.-born counterparts. Both African and U. S. -born men were more likely to have higher blood pressure rates than were the women, while the inverse was the case for BMI with both African and U. S. -born women being significantly more likely to be overweight or obese than their male counterparts. Overall, Africans residing outside the United States, both males and females, appear to be less likely to have elevated hypertension risk and were also less likely to be obese than African-born Blacks residing in the United States. However, they also tend to be younger and age is a known major risk factor to developing hypertension.

LIMITATIONS

Sixty percent (60%) of the men in the study by Yu et al[24] and 50% of the men in the study by O'Connor et al[23] had been in the Uke-

Table 6. *Pooled Analysis on Hypertension and BMI by Sex and Nativity-Outside the U.S vs U. S -Born*

Region	N (%)	Mean Age±SD†	sBP*	dBP**	BMI***
Males					
African Total - Average	4072 (51)	36.7±7.4	122.3±16.5	74±12.4	23.3±3.9
Caribbean Total - Average	2104 (26.4)	40.4±10	123±17.7	72±13.1	24±4.3
United States Total - Average	1795 (22.5)	40.7±10	126.5±14.3	77.8±12.5	27.7±6.0
Females					
African Total - Average	4642 (49)	35.7±7.5	115. 7±18.4	71.4±12.1	25.9±5.6
Caribbean Total - Average	2841 (30)	40.3±9.7	119.6±19.3	71.3±13.2	28.6±6.5
United States Total - Average	2000 (21)	39.7±9.8	120.4±19.3	75.2±12.5	31.4±7.8

*Notes: *Systolic blood pressure; **Diastolic blood pressure; ***Body mass index; † Cooper et.al[30] Mean Age±SD not provided*

gbu et al[25] study. As a result of the limited heterogeneity demonstrated by these three studies, it is hard to agree with the position that the healthy immigrant effect is no longer valid for Black African immigrants as posited by both Ukegbu et.al[25] and O'Connor et al.[23] In addition, all three studies[23-25] were conducted in Washington D.C., while the study by Hyman et al[26] was conducted in Houston. This lack of geographic diversity further limits the generalizability of these studies to the larger Black African population living in the United States.

All of the studies in this critical review were limited by their small sample size. Furthermore, Hyman et al[26] recruited only health professionals for their study, which implies a higher socioeconomic status that could further limit the generalizability of their results.

The studies comparing Black Africans living in their country of origin lacked information on cardiovascular health factors other than BMI and hypertension and thus did not allow for a complete health profile of African-born Blacks. Also, none of the papers identified for this review included information on access to health care or healthcare utilization. If information on these potential risk factors was available, it might have helped explain the observed differences in cardiovascular outcomes between U.S.-born and African-born Blacks.

Lastly, a simple pooled analysis may not be considered the gold standard for reporting aggregate data of studies as it might overlook potentially important subgroup characteristics.[33] However, research has shown that a pooled analysis has "*the ability to improve the power of small or inconclusive studies to answer questions and the ability to identify sources of diversity across various types of studies.*"[34]

IMPLICATION OF FINDINGS FOR FUTURE RESEARCH

African-born Blacks who served as subjects in the reviewed studies had an average length of stay in the United States of 10-years. It is not unreasonable to posit that length of stay is a proxy for acculturation and that it may be a risk factor for hypertension, high cholesterol and diabetes among immigrants. However, Hyman et al[26] reports that being African-born was protective against hypertension, despite the fact that over 80% of subjects in that study lived in the U.S. for 10-years or more. Moreover, a 2020 study by Ioannidis et al[35] showed no association between length of stay and cardiovascular health for the immigrant African Black. However, their study was unable to make a distinction about whether subjects of African descent identified as Afro-Caribbean, Hispanic or Latino.[35] These contradictions suggests that additional research is needed on environmental or lifestyle influences that impact cardiovascular health for various Black immigrant populations.

Okwuosa et al[19] suggested a genetic influence as the reason for the observed differences in cardiovascular diseases between African-born and U.S.-born Blacks. While genetic influences are beyond the scope of this review, future clinical studies should explore this hypothesis. In addition, future research should consider how social determinants of health put African-born Blacks residing in the United States at risk for CVD compared to U.S-born Blacks.

All of the studies in this review suggest that waist circumference ratio or body fat, as well as visceral adiposity, were associated with the poor cardiovascular health of African groups rather than BMI. Other studies have also shown this association.[31,36] More research is needed in this area and, if found to be consistent, should generate calls for a change in guidelines for cardiovascular risk factors.

For all of the studies in this review, the majority of the African-born Blacks were from West Africa, particularly Nigeria. Meyer et al[37] report that Nigerians tend to be highly educated, more likely to speak English as their first language, and more likely to be employed than their fellow Black Africans and the general U. S. -population. This suggests that Nigerians have a different profile and perhaps some confounding protective or risk factors compared to their counterparts from other African nations. Studies have also suggested a lower prevalence of hypertension among Black West Africans, with one study reporting prevalence ranging from 15% in West Africa to 25% in East Africa, and between 42% and 54% in South Africa.[30,31,38] This review observed the same effect among Black Africans living in Africa but found West and East Africans living in the United States to have similar or slightly higher rates.

Like Gomez-Olive et al[33] Cooper et al[9] found significantly higher rates of hypertension among Black South Africans.

Research suggests that the social status of Black people living in a country where they are a minority, and where there is marked residential segregation and economic inequality, is a major risk factor for poor cardiovascular health.[33,39-41] There needs to be further research on the links between racial bias and discrimination with cardiovascular health among minority Black populations as Black immigrants will no doubt face these issues upon migration.

CONCLUSION

Publications on the differences in cardiovascular health for African-born and U. S. -born Blacks in the United States are limited. This systematic review found only four papers that reported on a few cardiovascular risk factors, and all four had limitations that make them ungeneralizable to these populations as a whole. The secondary aim of this work was to identify studies where healthcare utilization was identified as a potential risk factor for the cardiovascular disparities observed between African-born and U. S. -born Blacks. Despite the fact that healthcare access and utilization have been found to be risk factors for poorer cardiovascular health for several populations in the United States,[42-44] none of the studies examined here evaluated these factors.

This review was unable to meet the two objectives, as the majority of the studies only reported BMI and hypertension rather than all seven cardiovascular health factors, and none examined healthcare utilization. Yet these results are an important contribution to the literature, indicating a very real need for future studies that can help close the gap in disparities between Blacks and Whites in the U.S. by understanding the diversity in the U.S. Black population. Spatz et al[45] found that the absence of a usual source of care, a healthcare utilization measure, was associated with being untreated for hypertension even among individuals with insurance. It is imperative that additional studies are conducted that examine the potential effect of healthcare utilization on the cardiovascular health of Blacks in the United States.

In a status report on hypertension in Africa, van de Vijver and colleagues[46] state that "*urbanization and changes in individual and societal lifestyle such as an increase in tobacco use, excessive alcohol consumption, reduced physical activity and adoption of 'Western' diets that are high in salt, refined sugar and unhealthy fats and oils*" contribute to steadily climbing hypertension and CVD rates in Africa. Considering this, there needs to be increased prevention efforts among the African-born immigrant populations in the United States, as well as early integration to the healthcare system to reduce the additional mortality burden which creates both a gap and economic burden on the American healthcare system.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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Case Report

Ebstein's Anomaly, Possible Newly Implicated Drug Aetiology? A Case Report

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ABSTRACT

Ebstein's anomaly is a congenital malformation of the heart that is characterized by downward displacement of an abnormal tricuspid valve into the right ventricle. It is rare, with an incidence of 1 in 200,000 live births. Etiology is unknown. Our patient was exposed to artemether-lumefantrine, ciprofloxacin, and ibuprofen (not previously linked with Ebstein's anomaly) at about four weeks of gestation. An obstetric scan at 33 weeks' gestation, was the first clue to the diagnosis.

Keywords
Ebstein's anomaly; Atrial septal defect (ASD); Nonsteroidal anti-inflammatory drugs (NSAIDs).

INTRODUCTION

Ebstein's anomaly is a congenital heart disease characterized morphologically by apical displacement and malformation of the tricuspid valve, dilation of the right atrium, small right and left ventricles, and usually an atrial septal defect (ASD).[1]

A striking aspect of Ebstein's anomaly is its varying clinical presentation based on the age at which it is detected. Its mode of presentation ranges from hydrops fetalis in utero and cyanosis in the newborn, a murmur or heart failure in an infant, an arrhythmia in an adolescent to incidental detection of an ASD in the elderly, all based on the degree of affectation of the tricuspid valve and other associated cardiac defects.[1]

In this case report, we describe Ebstein's anomaly in a Nigerian neonate, highlighting its spectrum of presentation across all age groups, highlighting the presentation, known etiology and its prognosis. Permission was granted by the mother to publish this case report.

CASE REPORT

A.B. a female neonate was delivered *via* spontaneous vaginal delivery to a 35-year-old para 4+0 to a Hepatitis B positive but human immunodeficiency virus (HIV) negative mother at a gestational age of 38-weeks. At approximately four weeks of gestation, mother developed fever, headache, right hypochondriac abdominal pain with malaise for which she used a 3-day adult course of artemether-lumefantrine, a 5-day course of ciprofloxacin 500 mg twice daily and ibuprofen 400 mg three times a day for 8-days. She presumed she had malaria, and commenced the self-treatment, although she did not undergo any laboratory testing to confirm her own assumption. She was subsequently diagnosed with pregnancy dated at 6-weeks gestation.

An obstetric scan at 33-weeks' gestation, revealed cardiomegaly and a dilated right atrium. There is no known family history of heart defects. She was referred to our facility and presented at 38-weeks in labor. Appearance, pulse, grimace, activity and respiration (APGAR) scores were 4 and 8 at the first and fifth-minutes respectively. Her weight was 2,670 g. She however remained centrally cyanosed despite regular respiratory excursions and administration of supplemental oxygen. Oxygen saturation was 66% in room air and 76% on intranasal oxygen.

Peripheral pulses and blood pressure (BP) were normal. The apex beat was displaced at the fifth left intercostal space and the trachea was central. Precordium was normoactive and there

was a systolic murmur, grade 3/6 was heard in the left lower sternal border. Heart rate was 158 beats per minute.

Chest radiography revealed cardiomegaly with a cardiothoracic ratio (CTR) of 0.7 (Figure 1). A QRS axis of 120°, tall *p* waves in lead V1, suggesting right atrial enlargement and low voltage QRS complexes in the left precordial leads, Figure 2. Echocardiography revealed a markedly dilated right atrium and a small left atrium. The tricuspid valve was displaced apically by 16 mm into the right ventricle with severe tricuspid regurgitation with a gradient of 30 mmHg. A large Secundum ASD 25 mm, with a right to left shunt, an intact ventricular septum. The pulmonary valve was stenosed. A diagnosis of an Ebstein's anomaly with a large Secundum ASD was established in the neonate. She was managed in the neonatal unit with anti-failure medication until her demise in the 2nd week of life.

Figure 1. *Chest Radiograph of Patient Showing Cardiomegaly*

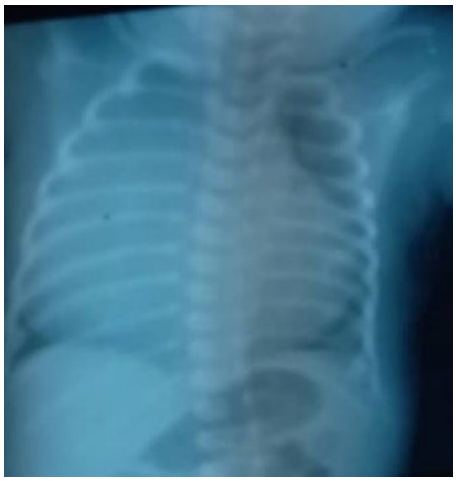


Figure 2. *Electrocardiograph of Patient*

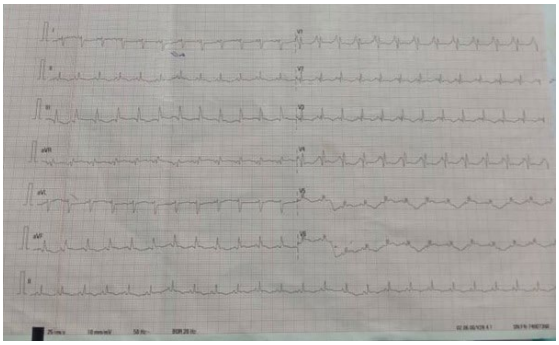
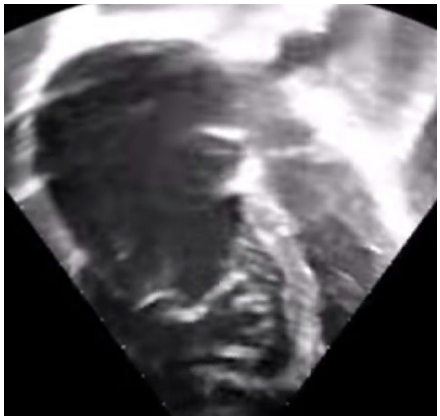


Figure 3. *2D-Echocardiography Showing a Markedly Dilated Right Atrium and a Small Left Atrium. The Tricuspid Valve was Displaced Apically by 16 mm into the Right Ventricle*



DISCUSSION AND CONCLUSION

Ebstein's anomaly was first described by Wilhelm Ebstein in 1866. Its characterized by malformation and downward displacement of the insertion of the septal and posterior leaflets of the tricuspid valve into the right ventricle. This valve displacement results in an enlarged right atrium due to the "atrialized" portion of the right ventricle and accompanying tricuspid regurgitation. The right ventricle is usually small and dysfunctional. The left ventricular size is usually normal, but it may be compressed by a dilated right ventricle. The left ventricle is also dysfunctional and maybe fibrotic.[1]

Ebstein's anomaly occurs in 1 in 200,000 live births it accounts for about <1% of all congenital heart diseases. In a series in Lagos by Animasahun et al[2] it accounted for 0.3% of all cyanotic congenital heart diseases.

The cause of Ebstein anomaly is unknown. Studies have linked the use of lithium for bipolar disorders in pregnant mothers and the use of benzodiazepines and marijuana to its occurrence.[3] There are also reports of genetic mutations leading to Ebstein's anomaly.[4] Artemether lumefantrine is safe in pregnancy and not linked to adverse outcomes in the foetus.[5] However, Schiebler et al6 in the United States reported a case of Ebstein's anomaly that occurred following a history of malaria in the mother in the sixth-week of pregnancy.[6] Maternal febrile illness in the first trimester of pregnancy has been considered a risk factor for the development of right obstructive heart defects.[7]

Fluoroquinolones are not linked with cardiac malformation.[8] Non-steroidal anti-inflammatory drugs (NSAIDs) are associated with some cardiac malformations but not with Ebstein's anomaly.[9] The mother had hepatitis B, which has not been linked with congenital heart diseases.[10]

The clinical presentation of Ebstein's anomaly is varied depending on the patient's age. In fetal life, cardiomegaly is the usual mode of presentation like in our patient. In newborns, cyanosis, heart failure, or murmur in infant, while arrhythmias or an incidental finding of an ASD is the presentation in adolescence and adulthood. The earlier the age at presentation, the worse the prognosis.[1]

In the newborn, symptomatology is due to ineffective ventricular output and severe tricuspid valve regurgitation. Massive cardiomegaly may lead to compression of the adjacent lungs leading to lung hypoplasia.[11]

Medical management is the mainstay of treatment in the first month of life. There's an increased risk of mortality of up to 36% if the surgery is done in the neonatal period. Supplemental oxygen, no more than a 21% fraction of inspired oxygen (FiO_2) may be used to ensure oxygen saturation of 75 and 85%.[11] Some neonates with severe Ebstein's anomaly and the normal pulmonary valve will benefit from closure of their ductus as this will improve forward flow across the pulmonary valve and decrease right ventricular pressure. Medications such as anti-failure, anti-arrhythmic drugs, and aspirin can be used from the neonatal period in those with severe Ebstein's anomaly to manage complications.

There's a high-risk of mortality from Ebstein's anomaly in the neonatal period and beyond. The causes of death include heart failure, hemodynamic instability, arrhythmias, and peri-operative complications.[9] Management in the neonatal period is daunting for the healthcare team even in the developed world. If new medications are linked to its occurrence, they need to be documented.

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To the parents of this newborn who gave consent write this case report to improve knowledge. We say thank you.

AUTHOR CONTRIBUTION

AA was the project leader, participated in the design and supervision, and manuscript writing. OA participated in manuscript writing, FL and ED participated in the conceptualization, design, supervision, and critical review of the manuscript. All authors read and approved the final manuscript.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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Assessment of Level of Awareness Towards Radiation Protection Among the Staff Working at Angiography Suite at Public Hospitals

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ABSTRACT

Introduction

Several challenges with radiation protection and safety culture in radiology departments needs to be addressed as few studies done in this aspect in our country. Especially with regard to the awareness about radiation protection, hazards, dosimetry usage and measurement.

Objective

The objective of this study is to find knowledge about radiation exposure hazard and practices among various auxiliary staff working in radiation units.

Material and Methods

Cross-sectional study done by using stratified random sampling method. A questionnaire made to check the awareness level of the radiological staff regarding radiation protection working in angiography suite. The questionnaire had two parts with various questions about radiation protection measures and safety related knowledge for staff and patient. Data collected from angiography suite of three public sector hospitals of Lahore, Pakistan. All the data entered in statistical package for the social science (SSPS) version 16 and analyzed for statistically significant outcomes.

Results

Total of 67 staff members were included in this study from three different public sector hospitals, 55.2% were males 44.77% were females. Twenty-nine (29) persons belonged to the age group of 20-30-years. Twenty (20) doctors, 21 nurses, 12 radiographers and 14 paramedical staff were included. 89.55% staff members were aware of radiation hazard. 55.22% had training on radiation protection and 44.77%. 56.71% were aware of dosimeter. Only 16% were aware of as low as reasonably achievable (ALARA).

Conclusion

The radiological staff members were partially aware about radiation hazards and radiation safety. They were lacking from training and workshops. Essential steps required to develop nationwide strategies for improving the situation and maintaining a safe working environment.

Keywords

Angiography; Radiation hazards; Radiation protection; X-ray; Radiation protection devices.

INTRODUCTION

In developing countries, about 3.6 billion imaging studies per year carried out worldwide, which leads to an increase of 70% collective effective dose for medical diagnostic procedures.[1] The knowledge of doctors about radiation doses exposure during diagnostic radiological procedures is lacking. Such information is important when the expansion of imaging technology is increasing.[2]

All radiology workers need proper monitoring and protection equipment. They must also acquire education and training during their jobs.[3] The level of training should be dependent upon the level of risk. The International Commission on Radiological Protection (ICRP) assumes the responsibility of providing

guidance in matters of radiation safety.[4] According to as low as reasonably achievable (ALARA), no practice relating exposures to radiation should be approved unless it produces a sufficient benefit to the exposed individual or to the society and in relation to any particular source within practice. The magnitude of individual doses, the number of people exposed and the likelihood of gaining exposures should be kept as low as reasonably achievable.[5] Mojiri et al[6] also revealed that 83.1% were aware of radiation hazards in her study and 78.9% used the safety measures to protect themselves. Mehmet et al[7] study revealed that about 50% of health care workers had less knowledge about radiation protection awareness.

There was limited study on awareness of radiation hazards and radiation protection among medical staff working in angiography suite found in low socio-economic country as Pakistan. Therefore, this study was was performed to assess the level of knowledge about awareness regarding radiation protection.

MATERIALS AND METHODS

This is a cross-sectional study aiming to survey healthcare professionals working in angiography suite with regard to their knowledge or aware of radiation protection. A semi-structured, close-ended questionnaire used as a data-collecting tool after pre-testing to check the reliability of the questionnaire. The reliability of the questionnaire was 70% in this study by using Cronbach's Alpha. Data collected prospectively from angiography department of three public sector hospitals i.e., The Children hospital, General hospital and Gulab Devi hospital, Lahore, Pakistan after the approval of institutional review board (IRB). Duration of the study was 6-months, from September 2020 to March 2021. Staff members were divided into four groups. First group consisted of cardiologist and neurologist, the second group consisted of nurses, the third one radiographers and fourth para-medics working only in angiography suite.

The questionnaire had mainly three parts with various questions around radiation protection and safety related to staff and patients. The first part contained information about demographic data like age, gender and working experience, etc. The second part was about the awareness of employees around radiation protection and protection devices and the third part was about the implementation of the safety measures and the hard copies were distributed.

Including Criteria

Data are collected only from angiography suite of three public hospitals of Lahore after their consent.

Excluding Criteria

1. Non-ionizing modalities like magnetic resonance imaging (MRI), ultrasound (US) and echocardiography (ECG). Other ionizing modalities such as X-rays, computed tomography (CT), fluoroscopy, positron emission tomography (PET) scans, single-photon emission computed tomography (SPECT) scans, nuclear medicine were excluded from the study.
2. Incomplete questionnaires, members from whom we failed to receive the consent regarding participation in the study.

Statistical Analysis

All data were entered in statistical manner for the social sciences (SSPS) version 16 and then analyzed for statistically significant outcomes. Descriptive analysis was used to check the frequency and percentage. While Pearson chi-square (χ) used to check the association between categorical variables. Cronbach's alpha was used to measure the consistency and was found to be 70%.

RESULTS

Out of 67, 37(55.22%) were males and 30(44.77%) were females. Most of the staff members belonged to the age group of 20-30-years.There were 20 doctors, 15 cardiologists and 5 neurologists. Twenty-one (21) nurses, 12 radiographers and 14 paramedical staff in the study groups working at angiography suite (Table 1), 89.55% staff members were aware of radiation hazard. Only 47.76% took all the all the safety measures i.e., lead aprons, thyroid shields and lead glasses, while 28(41.79%) used only lead aprons and 7(10.44%) people used lead aprons and thyroid shield only.

Table 1. *Demographic Data*

		Current Designation						
		Cardiologist	Neurologist	Nurses	Paramedics	Radiographer	Total	*p* Value
Gender	Male	8	4	12	1	12	37	0
	Female	7	1	9	13	0	30	
Age	20-30-Years	6	2	8	8	5	29	0.13
	31-40-Years	5	1	8	3	5	22	
	41-50-Years	3	0	5	3	2	13	
	51-60-Years	1	2	0	0	0	3	
Working Experience	1- 4-Years	7	2	3	6	2	20	0.38
	5 -9-Years	3	1	6	4	3	17	
	10-14-Years	1	0	7	2	5	15	
	≥14-Years	4	2	5	2	2	15	

Twenty-eight (28)(41.79%) used glass shield at head side, 13(19.40%) at leg side, 3(4.48%) at lateral side, 21(31.34%) were not aware of safety measures and 2(2.98%) did not answer. Regarding handling of lead aprons 53(79.10%) hanged the lead aprons on the hangers and 14(20.89%) did not know about it (Table 2).

Regarding awareness, 37(55.22%) completed the training on radiation protection and 30(44.77%) never took training on radiation protection. 38(56.71%) were aware of dosimeter and only 45(67.16%) were aware of ALARA (Table 3). Interestingly, out of all the staff members, 70% consultants were not trained on radiation protection and 45% consultants were unaware of dosimeter and ALARA.

Only 30(44.77%) staff members were aware of implemented ALARA and 22 (32.83%) were not aware of ALARA. Out of which 7(10.45%) implemented ALARA by decreasing time, 1(1.49%) increased distance between radiation source and operator, 1(1.49%) used shield, 6(8.96%) decreased time and increased distance between source and operator (Figure 1). It was found that

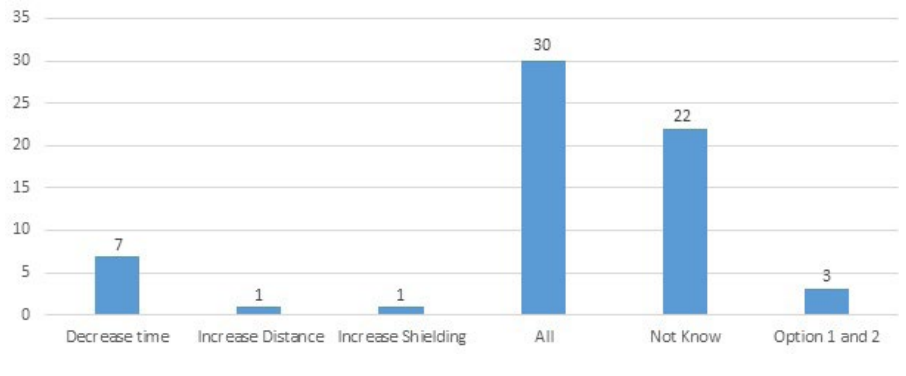
Table 2. *Radiation Protection Measures in Study Groups*

		Current Designation						
		Cardiologist	**Neurologist**	**Nurses**	**Paramedical Staff**	**Radiographer**	**Total**	***p* Value**
Radiation Hazard	Yes	14	5	21	14	6	60	0
	No	1	0	0	0	6	7	
Safety Measures	Lead aprons	8	2	2	4	12	28	0
	All	7	3	15	7	0	32	
	Option 1 & 2	0	0	4	3	0	7	
Glass Shield	Leg side	3	2	3	5	0	13	0
	Lateral side	0	0	3	0	0	3	
	Head side	7	3	13	5	0	28	
	Others	2	0	0	0	0	2	
	Not aware	3	0	2	4	12	21	
Apron Handling	Hang it on hangers	15	5	21	12	0	53	0
	Not aware	0	0	0	2	12	14	

Table 3. *Awareness about Radiation Protection in Study Group*

		Cardiologist	**Neurologist**	**Nurses**	**Paramedical Staff**	**Radiographer**	**Total**	***p* Value**
Training on radiation protection	Yes	5	1	18	9	4	37	0.003
	No	10	4	3	5	8	30	
Dosimeter	Yes	7	4	20	7	0	38	0
	No	8	1	1	7	0	17	
	Not Aware	0	0	0	0	12	12	
ALARA	Yes	8	4	21	12	0	45	0
	No	7	1	0	2	12	22	

Figure 1. *ALARA Implementation*



40% consultant and 14% paramedics did not implement ALARA, while 100% nurses implemented ALARA measures (Table 4).

Regarding patient protection, 27(40.29%) implemented minimum procedure time to protect patient from radiation hazard, 5(7.44%) reduced distance between patient and detector, 8(11.9%) used shield, 3(4.48%) applied all the safety measures, 11(16.42%) implemented both minimum time and reduced distance between patient and detector and about 13(19.40%) people this question was not applicable (Figure 2).

For reducing exposure factors, 3(4.48%) increased kvp and decreased mas, 8(11.94%) collimate the area of interest, 3(4.48%) decreased the use of cine angiography, 9(13.43%) used all (increase kvp and decreased mas, collimate the area of interest, decreased use of cine angiography copper filtration), 4(5.97%) decreased used of cine angiography and collimate area of interest, and 40(59.70%) were not aware of exposure factors used during the angiographic procedures (Figure 3).

Regarding workshops and guidance, 7(10.44%) attended 3 workshops in a year, 7(10.45%) attended 5, 21(31.34%) attended 1 workshop in a year and 32(47.76%) never attended any workshops on radiation protection in a year. Out of 67, 37(55.22%) persons guided their juniors by teaching, 7(10.45%) held workshops to guide their juniors, 5(7.46%) used both (workshops and teaching method), 4(5.97%) used some other methods to guide their students and about 14(20.89%) persons mentioned that, this question

Table 4. *ALARA Implementation in Study Groups*

		Cardiologist	Neurologist	Nurses	Paramedical Staff	Radiographer	Total	*p* Value
ALARA Implementation	Decrease time	1	0	6	0	0	7	0
	Increase distance	0	0	0	1	0	1	
	Increase shielding	1	0	0	0	0	1	
	All	6	4	13	7	0	30	
	Not know	7	1	0	2	12	22	
	option 1 & 2	0	0	2	4	0	6	

Figure 2. *Patient Protection Measures Used in Study Group*

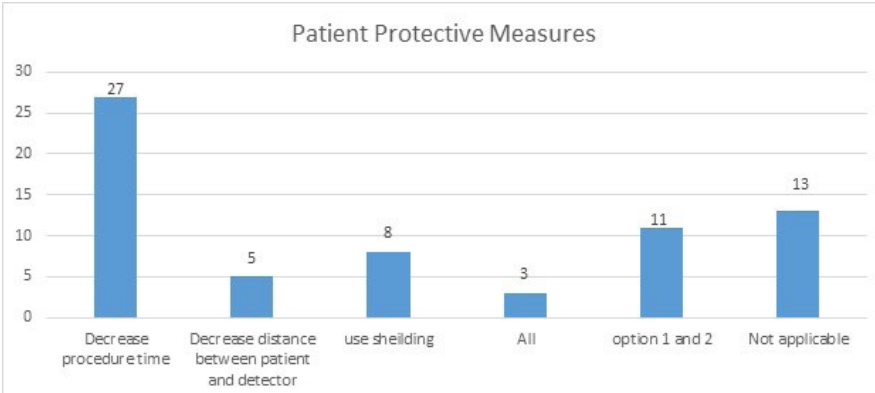


Figure 3. *Reducing the Exposure Factors in Study Group*

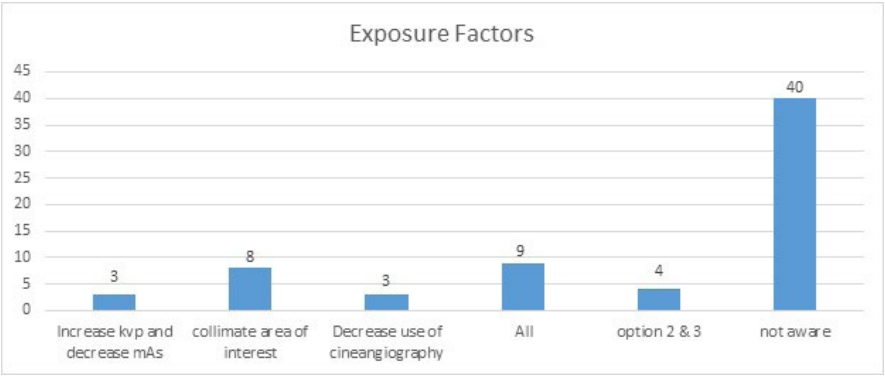


Table 5. *Mode of Creating Awareness to Juniors*

	No. of Workshops	Cardiologist	Neurologist	Nurses	Paramedical Staff	Radiographer	Total	*p* Value
Radiation hazard safety measures	3	2	0	4	1	0	7	0.002
	5	1	0	6	0	0	7	
	1	4	3	6	8	0	21	
	Never attended	8	2	5	5	12	32	
Glass shield	By teaching	8	2	20	7	0	37	0
	By workshop	3	1	0	3	0	7	
	Both	3	1	1	0	0	5	
	Other method	1	1	0	2	0	4	
	Not applicable	0	0	0	2	12	14	

was not applicable at all (Table 5).

DISCUSSION

Our study revealed that 89.55% healthcare workers were aware of radiation hazard and only 70.1% health workers working at angiography suite used safety measures out of which only 47.76% used all the safety measures. Majority of them were radiographers. In the health worker group, 20.89% cardiologists, 7.46% neurologists, 8.96% radiographers, 31.34% nurses and 20.89% paramedical staff were aware about the radiation hazard. The implementation of recommended radiation protection protocols and practices in the radiology departments is vital for the safety of the radiographers, the patients and the environment.[8] Mojiri et al[6] also revealed that 83.1% were aware of radiation hazards in her study and 78.9% used the safety measures to protect themselves. Mehmet et al[7] study revealed that about 50% of health care workers had less knowledge about radiation protection awareness. Lynskey et al[9] study showed that 99% used lead aprons, 94% used thyroid shields and 54% used lead glasses, 44% used ceiling suspended lead shields. Our study showed that 99% staff used lead aprons and 93% used thyroid shield. Abuzaid et al[10] showed that radiographer compliance related to patient protection and self-protection were 64.4% and 45.7% respectively, overall radiation protection practice compliance was 75.2% ±18.5. But in our study 47.77% used overall radiation protection practice in public sector hospital.

In our study, only 67.1% health care workers in angiography suite knew ALARA implementation. Abuzaid et al[10] study also showed lower radiation exposure factors used i.e., 43.7, 46.4 and 38.5%. Nevertheless, increase awareness is necessary to improve current practices. The ALARA concept is an essential theme in radiation protection in medicine. The three major principles of applying ALARA are time, distance and shielding. Radiographers can effectively improve radiation protection through compliance with the established international guidelines and standards of practice and by utilizing proper tools and equipments. The current study revealed that, currently, radiographers' practices are unsatisfactory about reducing radiation exposure for patients and themselves.[10] Therefore, a systematic and harmonized approach is required in the form of proper actions to ensure that radiation protection measures and standards should be implemented in radiology departments.

Radiation exposure factors was done by 46.26% in our set up and 56.71% were aware of dosimeter in our study, which was alarming. Briggs-Kamara et al[11] showed that 76.2% of radiographers use proper collimation. Eze et al[12] reported a better attitude to wearing radiation dosimeters among a sample of industrial radiographers in Port-Harcourt, Nigeria. The periodic radiation dose check is lacking in our public sector hospitals. Concerning the utilization of the patient protection tools, the study revealed that 10.2, 24.4 and 15.7% of the participants neglected to use the light beam diaphragm, cone and gonads shielding, respectively.[12,13] In our study it showed that patient protection measures used in 80.59% with different measures.[14]

Our study revealed lack of awareness regarding radiation protection along with implementation of ALARA in doctors and workers in angiography suite. There is also lack of study in this aspect in our country. We need to improve it by conducting frequent workshops, awareness programs and seminars.

CONCLUSION

Awareness regarding radiation protection in health care workers in angiography suite were unsatisfactory. The head nurse and radiographers should guide to implement ALARA. Workshops, webinars, training courses, meetings and teaching for radiation protection should be increased. By following the radiation protection guidelines, we can protect others and ourselves from the harm full hazards of radiations.

LIMITATIONS

Small sample size. More hospitals should be involved including private sector. Survey should be done at country-level.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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