

The relationship between clinical parameters and the risk of mortality or requiring the insertion of a pacemaker in patients with bifascicular block

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ABSTRACT

Introduction: Patients with bifascicular block (BFB) are at risk of progressing to high-degree atrioventricular block (AVB) and have a higher mortality risk. This study aimed to identify relationships between clinical parameters in patients with BFB and the risk of mortality and/or requiring permanent pacemaker (PPM) insertion, to better risk-stratify and appropriately investigate patients at the time of diagnosis in a resource-limited setting.

Method: A descriptive study was conducted via retrospective review of all patients who received an electrocardiogram (ECG) during 2014 at Tygerberg Hospital (TBH), South Africa. In total, 16 280 ECGs were assessed, accounting for 11 881 patients (some patients had more than 1 ECG), and those with BFB were identified. Patients' records were assessed at the time of diagnosis and followed for 10 years to identify relationships between clinical parameters in patients with BFB and mortality or requiring a PPM.

Results: Of the 11 881 patient ECGs assessed, 140 patients with BFB were identified. The mean age at diagnosis was 62 ± 17 years. Of these patients, 37 (26%) died, and 9 (6%) required a PPM. The mean age at diagnosis of deceased patients was 66 ± 12 years ($p = 0.07$). Significant relationships with mortality included diabetes mellitus (DM) ($p = 0.04$) and a reduced left ventricular ejection fraction (LVEF) ($p = 0.05$), with age and hypertension related at a lower level of significance ($p = 0.07$ and $p = 0.06$, respectively). Significant relationships with PPM insertion were symptom presence at diagnosis ($p \leq 0.01$) and PR interval prolongation at a lower level of significance ($p = 0.08$).

Conclusion: In patients with BFB, DM, hypertension, age, and a reduced LVEF had the most significant relationships with mortality. Symptoms and a prolonged PR interval had the most significant relationships with requiring a PPM. Mortality in patients with BFB is more likely to be related to standard risk factors, such as DM, hypertension, age, and a reduced LVEF, than the conduction defect per se.

Keywords: bifascicular block, mortality, pacemaker.

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INTRODUCTION

The prevalence of bifascicular block (BFB) is estimated at 1–1.5% in the general population.⁽¹⁾ The mortality rate for this population ranges from 2% to 14%, which is higher than that of an age- and sex-matched population without BFB.⁽¹⁻³⁾ Patients with a bundle branch block have at least a threefold higher mortality risk after 10 years from diagnosis compared with patients who have narrow complexes.⁽¹⁾ BFB is often perceived to be prone to progression to third-degree atrioventricular block (AVB), as it involves 2 of the 3 fascicles in the His-Purkinje System (right bundle branch block [RBBB] with either left anterior or left posterior fascicular block [LAFB/LPFB]), with conduction depending on the remaining fascicle.⁽⁴⁾ However, the reason for this higher mortality rate is multifactorial, with intrinsic organic cardiac disease and the risk of developing high-degree AVB and ventricular arrhythmias.⁽⁴⁾

The incidence of progression to high-degree AVB is reportedly low, with previous studies reporting an annual incidence of 1%.^(3,5) Symptomatic BFB, defined as unexplained presyncope or unexplained syncope, can be effectively managed with permanent pacemaker (PPM) insertion.^(6,7) However, according to previous studies, there is no mortality benefit of

PPM insertion, suggesting that the cause for mortality in these patients is not related to the development of high-degree AVB, but rather organic cardiac disease and/or ventricular tachyarrhythmias.^(4,8) Predictors of mortality or developing high-

degree AVB have been investigated previously; however, these studies were conducted in developed settings with easy access to both electrophysiology study (EPS) and PPM insertion.

Cardiac failure, with an advanced New York Heart Association (NYHA) Functional Classification, hypertension, advanced age, atrial fibrillation (AF), and renal impairment were independent predictors of mortality in patients with chronic BFB.^(6,9,10) Factors noted to predict progression to high-degree AVB were indicated by symptom presence, a His-bundle ventricular (HV) interval > 64 ms, a QRS duration > 140 ms, and renal dysfunction.⁽¹¹⁾ To our knowledge, no studies in Africa have attempted to assess the relationships between clinical parameters and mortality or requiring pacing in patients with BFB.

Current guidelines from the American College of Cardiology (ACC) and the European Society of Cardiology (ESC) for investigating and managing patients with symptomatic BFB require significant expertise, may not be cost-effective, and can therefore be challenging in a resource-limited setting.^(12,13) This study aimed to identify relationships between patients with BFB and mortality or progression requiring PPM insertion, to better risk-stratify and appropriately investigate patients at the time of diagnosis in a resource-limited setting.

METHODS

Study design

A descriptive, observational study was conducted via retrospective review. Patients with BFB were identified by screening all electrocardiograms (ECGs) performed at Tygerberg Hospital (TBH) during 1 year, and their clinical data were collected by reviewing hospital records over 10 years. All ECGs were accessed using the MUSE platform and were individually assessed by the investigators for BFB identification. Data analysis was performed to establish relationships between the identified variables and endpoints. The primary endpoints were all-cause mortality or PPM insertion. Ethical approval was obtained from the Health Research Ethics Committee (reference number: N22/07/086).

Patient population

All ECGs performed at TBH and stored on the MUSE system during 2014 (1 January to 31 December) were individually assessed by the investigators to identify patients with BFB. BFB was defined by RBBB with either LAFB or LPFB. RBBB was defined as per the standard definition.⁽¹⁴⁾ LAFB was defined as a mean frontal QRS axis < -45° with a qR pattern in lead aVL, rS pattern in leads II, III, aVF, a R-peak time > 45 ms in lead aVL, and

TABLE I: Descriptive analysis assessing the relationship between variables in patients with bifascicular block and mortality or requiring a pacemaker.

Variables	Total patients (n = 140)	Total demised (n = 37)	Total survived (n = 103)	p-value	Required PPM (n = 9)	Did not require PPM (n = 131)	p-value
Age at diagnosis Mean (SD)	62 (17)	66 (12)	60 (18)	0.07	63 (18)	62 (17)	0.83
Sex, male n (%)	95 (68)	24 (65)	71 (69)	0.68	6 (67)	89 (68)	1.00
Symptomatic at presentation n (%)	18 (13)	3 (8)	15 (15)	0.40	5 (56)	13 (10)	< 0.01
Smoking n (%)	43 (31)	12 (32)	31 (30)	0.84	3 (33)	40 (31)	1.00
Hypertension n (%)	95 (68)	30 (81)	65 (63)	0.06	4 (44)	91 (70)	0.15
Diabetes mellitus n (%)	44 (31)	17 (46)	27 (26)	0.04	2 (22)	42 (32)	0.72
Ischaemic heart disease n (%)	61 (44)	19 (51)	42 (41)	0.33	2 (22)	59 (45)	0.30
Hypercholesterolaemia n (%)	66 (47)	17 (46)	49 (48)	1.00	4 (44)	62 (47)	1.00
eGFR < 60 ml/min/1.73 m ² n (%)	31 (22)	9 (24)	22 (21)	0.82	3 (33)	28 (21)	0.41
PR interval > 200 ms n (%)	17 (12)	4 (11)	13 (13)	1.00	3 (33)	14 (11)	0.08
Atrial fibrillation n (%)	19 (14)	8 (22)	11 (11)	0.16	3 (33)	16 (12)	0.11
Ejection fraction Mean (SD)	51 (14)	46 (14)	53 (13)	0.05	55 (11)	51 (14)	0.56

eGFR: estimated glomerular filtration rate, n: number, PPM: permanent pacemaker, SD: standard deviation.

the absence of other causes for left axis deviation (e.g. inferior myocardial infarction [MI]).⁽¹⁵⁾ LPFB was defined as a mean frontal QRS axis $> 90^\circ$ with a rS pattern in leads I and aVL, and a qR pattern in leads III and aVF in the absence of other causes for right axis deviation.⁽¹⁵⁾

Patients were included in the study if they were older than 18 years and had at least 1 12-lead ECG conducted during the study period. Patients were excluded from the study if they had pre-existing second- or third-degree AVB or a life expectancy < 1 year due to other chronic illnesses. Patients' demographic information and whether they were asymptomatic or symptomatic (any history of unexplained presyncope or syncope), smoking history, chronic comorbidities, coexisting cardiac disease, AF, and left ventricular ejection fraction (LVEF) at the time of diagnosis were documented. All patients who were not documented as having experienced syncope, presyncope, or dizziness were considered asymptomatic.

All biochemistry data were obtained from the South African National Health Laboratory Service, and renal function was assessed using the Modification of Diet in Renal Disease (MDRD) formula to calculate the estimated glomerular filtration rate. Valvular heart disease (VHD) was considered significant if the lesion severity was graded at least moderate, per the ACC guidelines for managing patients with VHD, or if the patient had prior valve replacement.⁽¹⁶⁾ Other conduction abnormalities (first-degree AVB, AF, and atrial flutter) were defined as per their standard definitions.^(17,18)

Statistical analysis

Normally distributed data were presented as means with standard deviations. Categorical data were presented as percentages. We assessed the relationships between each clinical characteristic and LVEF and each of the 2 endpoints (i.e. mortality and requiring PPM insertion), using analysis of variance (ANOVA), with a least significant difference (LSD) test, chi-squared test, and Fisher's exact test where appropriate. Clinical characteristics were used for comparison when there were more than 10 cases for a specific characteristic or variable. A p -value ≤ 0.05 was considered statistically significant, and a p -value of 0.05–0.1 was significant at a lower level of significance.

RESULTS

A total of 16 280 ECGs were assessed, representing a patient population of 11 881 (some patients had more than 1 ECG in 2014). Of these, 140 patients had BFB, with a prevalence of 1.18% among adults receiving ECGs at TBH in 2014. The mean age was 62 ± 17 years, and 95 patients (68%) were male. RBBB with LAFB was present in 86 patients (61%). At the initial diagnosis, asymptomatic patients accounted for 122 (87%) of the total cohort. AF was identified in 19 (14%) of the cohort, and 17 (12%) had first-degree AVB. Congenital heart disease was noted in 17 patients (12%). Of the total cohort, 95 patients (68%) had hypertension, and 44 (31%) had diabetes mellitus (DM). One patient (1%) in the study population had sarcoidosis,

and 2 (1%) had hypertrophic cardiomyopathy (HCM). Echocardiography was performed around the time of diagnosis in 86 patients (61%), with a mean LVEF of $51\% \pm 14\%$. A total of 37 patients (26%) demised, and 9 patients (6%) required PPM insertion. The clinical characteristics of the study population are summarised in Table I.

Mortality

The study population's all-cause mortality comprised 37 patients (26%). These patients were older, with a mean age of 66 ± 12 years at the time of initial diagnosis compared with the rest of the cohort, who had a mean age of 60 ± 18 years ($p = 0.07$). The mean age at the time of demise was 71 ± 13 years (5 years after diagnosis). Of the patients who demised, 24 (65%) were male. This mortality group had a higher prevalence of comorbidities compared with the rest, with 30 (81%) of the mortality group having hypertension versus 65 survivors (63%) ($p = 0.06$), and 17 (46%) with DM versus 27 survivors (26%) ($p = 0.04$) (Table I). The mean LVEF in the mortality group was $46\% \pm 14\%$, compared with $53\% \pm 13\%$ in the survivors ($p = 0.05$). In the mortality cohort, 29% of patients had a LVEF $< 35\%$.

The cause of death could be determined in 35/37 patients who died (Figure 1). Sudden cardiac death (SCD) or death resulting from a documented arrhythmia was not found in any of the 35 cases. The most common causes of death were heart failure ($n = 11$, 30%) and malignancy ($n = 7$, 19%). Two patients (5%) had an unknown cause of death; 1 was symptomatic at the time of diagnosis but only demised 5 years thereafter. He was never paced due to the loss of cardiology follow-up while being investigated. None of the other demised patients developed indications for pacing. Statistically significant relationships between patients with BFB and mortality, using the chi-squared test with Fisher's exact test, were DM ($p = 0.04$) and a reduced LVEF at initial diagnosis ($p = 0.05$). Due to the small sample size, using a p -value < 0.1 (considered significant at 10%), hypertension ($p = 0.06$) and age ($p = 0.07$) may also be considered significant (Table I).

Required pacing

Pacing was required in 9 patients (6%). The only statistically significant relationship between patients with BFB and those who required a PPM was symptom presence ($p \leq 0.01$). Due to the small sample size reaching this endpoint, PR interval prolongation ($p = 0.08$) may also be considered significant at a lower level of significance ($p < 0.1$) (Table I). The mean age at diagnosis was 63 ± 18 years, compared with 62 ± 17 years in the population that did not require pacing ($p = 0.83$). The mean age at the time of PPM insertion was 66 ± 18 years (3 years after initial diagnosis, with a range of less than 1 month to 7 years). Regarding comorbidities, there were no statistically significant differences between patients requiring pacing and those not requiring pacing, except for a numerically higher presence of first-degree AVB in those who required pacing ($n = 3$, 33%) compared with those who did not ($n = 14$, 11%) ($p = 0.08$).

VHD was present in 2 patients (22%), with 1 requiring PPM insertion post-valve replacement. Indications for PPM insertion

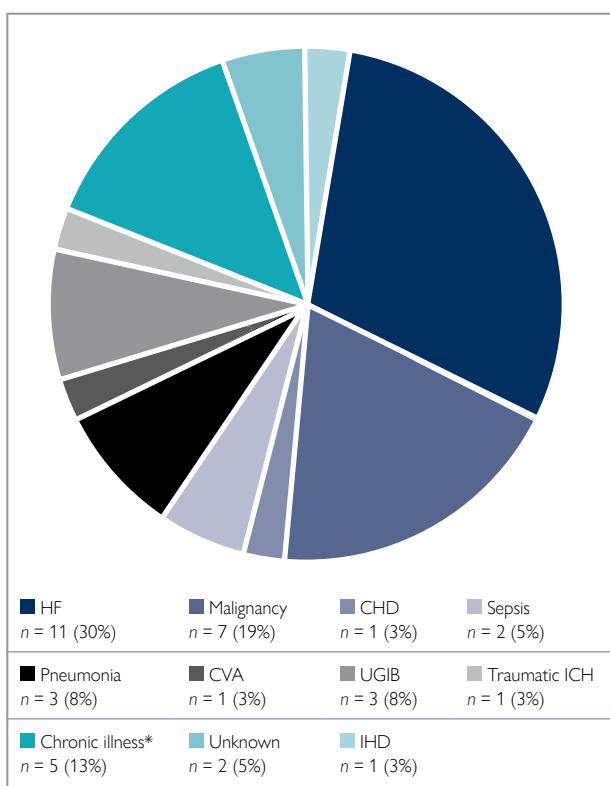


FIGURE 1: Cause of mortality in patients presenting with bifascicular block.

* See Table I for chronic illnesses per patient.

Patient 1: Diabetes mellitus, hypertension, hypothyroidism, previous cerebral vascular accident with scar epilepsy, peripheral vascular disease with previous above-knee amputation, pancreatic insufficiency, and bed-bound prior to death.

Patient 2: Diabetes mellitus, hypertension, hypercholesterolaemia, previous cerebral vascular accident, benign prostatic hyperplasia with a permanent suprapubic catheter in situ, and noted to have poor functional status before death.

Patient 3: Diabetes mellitus, hypertension, intracranial haemorrhage, chronic kidney disease, dementia, and poor functional status (bed-bound), long-standing before death.

Patient 4: Diabetes mellitus, hypertension, intracranial haemorrhage with previous coronary bypass surgery, reduced left ventricular ejection fraction, and previous central retinal artery occlusion (no documented cardioembolic cause).

Patient 5: Hypertension, chronic obstructive airway disease, kidney impairment, left arm axillary artery occlusion requiring embolectomy (no documented cardioembolic cause), and dementia with note of having a poor baseline function.

CHD: congenital heart disease, CVA: cerebral vascular accident, HF: heart failure, ICH: intracranial haemorrhage, IHD: ischaemic heart disease, n: number, UGIB: upper gastrointestinal bleed.

comprised mostly complete AVB ($n = 6$, 67%), with 1 (11%) developing 2:1 AVB, 1 (11%) developing symptomatic Mobitz type 1 AVB on exertion, and 1 (11%) developing sinus node dysfunction. Five of the 9 patients (55%) who required pacing were symptomatic at the time of diagnosis ($p \leq 0.01$). Of the 4 remaining patients who required pacing, 2 (50%) developed symptoms (1 with 2:1 AVB and the other with complete AVB),

and 2 (50%) had higher-grade AVB identified incidentally (post-aortic valve replacement and prior to elective cataract surgery). Therefore, 7 patients (78%) who required pacing were either symptomatic at the time of diagnosis or developed symptoms later.

DISCUSSION

This study indicates that patients with BFB are more likely to die from their comorbidities, which are well-known predictors of mortality in the general population, rather than from the undiagnosed progression of their conduction deficit leading to fatal, complete AVB. The presence or development of symptoms of unexplained presyncope or syncope, and possibly other conduction delays, such as first-degree AVB, may be associated with developing more significant conduction system disease.

Of the mortality group, 35 patients (95%) had an identified cause of death, with no documented SCD or high-degree AVB documented at the time of death. However, the 2 patients (5%) with unknown causes of death may have died because of SCD and possible high-degree AVB. Only 1 of these 2 patients was symptomatic at diagnosis; however, standard ECGs and Holter examination revealed no bradycardia or ventricular tachycardia, and the patient was lost to cardiology follow-up before further investigations.

Our study's 26% mortality rate is similar to those reported in previous studies by Martí-Almor, et al. (21%), McAnulty, et al. (29%), Tabrizi, et al. (33%), Rivera-López, et al. (33%), and Dhingra, et al. (38%).^(3,5,6,10,11) The similar all-cause mortality rates in our study compared with previous studies echo the narrative that the mortality risk in patients with BFB arises from their comorbidities and advancing age rather than conduction disease progression. This was previously reported in studies where PPM insertion did not reduce mortality. Impaired left ventricular function was also a significant contributor to mortality risk, with the mean LVEF being lower in the mortality group. Heart failure accounted for 11 (30%) of the total mortality cohort, and of these patients who had echocardiography around the time of diagnosis, 6 (56%) had a LVEF < 35%.

Therefore, our study's findings align with previous studies that have shown a higher mortality rate in patients with heart failure and BFB. These studies showed that patients with more advanced heart failure and a NYHA functional tolerance classification ≥ 2 with interventricular conduction delays have a higher all-cause mortality than patients with narrow QRS complexes.^(19,20) The significance herein may also relate to the rate of possible SCD and to the reason previous studies have not shown improved SCD rates with PPM insertion, as these patients are at high risk for ventricular arrhythmias, which is likely the largest risk factor for SCD rather than high-degree AVB.

The rate of SCD in our study is assumed to be $\leq 5\%$, as mentioned above, compared with 42% and 14% previously recorded by McAnulty, et al. and Tabrizi, et al., respectively.^(3,10) The wide range in these studies' rates can likely be attributed to

the difficulty of documenting such arrhythmias if patients do not present with them or are not on continuous monitoring at the time of death. Therefore, this rate may be higher, as the patients with severely impaired LVEF dying of heart failure may have died of undocumented ventricular arrhythmias. Due to this high mortality rate in such patients, current guidelines indicate implantable cardioverter-defibrillator (ICD) insertion with or without cardiac resynchronisation therapy (CRT) for symptomatic patients with a poor LVEF (< 35%).^(21,22)

The presence of symptoms at diagnosis did not have a statistically significant association with mortality. In our study, no patients who required pacing demised. This suggests that progression to high-degree AVB, which may result in SCD, is a gradual process. Patients then present to healthcare facilities with symptomatic progression of disease or high-degree AVB, which is found incidentally with routine follow-up and investigation. However, this finding is influenced by the small cohort size and, therefore, its significance cannot be confidently asserted. The significant difference in the relationships with mortality and requiring pacing suggests that the risk of SCD due to high-degree AVB is low, and that patients with BFB are at higher risk of death due to causes other than high-degree AVB, as described above.

Symptom presence (at the time of diagnosis or later) was the most significant variable for pacing ($p \leq 0.01$). The presence of symptoms is known to be 1 of the most important predictors for requiring pacing, as shown in a study by Marti-Almor, et al.; however, in their study, all patients underwent EPS, and the most significant predictor for requiring pacing was an HV interval > 64 ms.^(3,11,22) This was not investigated in our study, as EPS was not available at TBH at the time. Furthermore, 41% of patients in their study required pacing, compared with the 6% in ours.⁽¹¹⁾ This was likely due to the inclusion of mostly symptomatic patients in their study (87% compared with 13% in our study), as well as EPS being performed in each patient, with lower thresholds for PPM insertion than suggested by guidelines.⁽²²⁾

Of our total cohort, 18 patients (13%) were symptomatic at diagnosis; 5 received a PPM for the indications described above, and the remaining 13 did not receive a PPM. Of these 13 patients, 7 had a cardiac cause other than high-degree AVB, or other pathological bradycardias (e.g. sinus node dysfunction) for their symptoms, and 2 had symptoms attributed to non-cardiac disease (e.g. neurological). The remaining 4 were regrettably not investigated fully for a cause, but none of them died during the 10-year follow-up. Only 1 of the 13 patients had an implantable loop recorder (ILR) inserted. This patient had known HCM based on cardiac magnetic resonance (CMR) imaging with no outflow obstruction. The ILR showed 1 episode of sinus arrest for 4 seconds, 1 episode of non-sustained ventricular tachycardia, and no high-degree AVB. After further investigation, the patient's symptoms were attributed to an unspecified neurological cause.

According to the ACC and ESC guidelines,^(12,13) asymptomatic patients with BFB do not require any specific investigations, but are counselled on danger signs and advised to seek medical attention when experiencing these symptoms. Symptomatic

patients, however, require further investigation in order to identify intermittent high degree AVB. If a standard 12-lead ECG and/or Holter does not identify any bradyarrhythmia, the next investigation is echocardiography to assess the patient's LVEF. If the LVEF is $< 35\%$, the recommendation is that the patient receives an ICD/CRT-D due to the high risk of mortality in patients with heart failure and intraventricular conduction deficits as described above (class I evidence). If the LVEF is $> 35\%$, the recommendation is to perform EPS which, if positive (HV interval > 70 msec or second or third degree AVB on incremental atrial pacing or pharmacological challenge), the patient will require a PPM. If EPS is negative, the next step is for ILR insertion and assessment for high degree AVB. If no high degree AVB is captured, clinical follow up is recommended. According to these guidelines, empirical PPM insertion is also reasonable for patients with BFB and unexplained syncope (negative work-up as above and no other identified cause of syncope) or in patients at high risk for traumatic recurrence (e.g. elderly patients). The algorithm for EPS and ILR prior to PPM insertion has been shown to be effective in reducing the rate of syncope recurrence after PPM insertion whereas patients with empirical pacing may undergo an unnecessary procedure and still have recurrent syncopal episodes.⁽¹²⁾ Two patients in our cohort received an ILR, one of which had a positive finding of complete AVB and received a PPM. The other eight patients who required pacing had their indication for pacing identified on standard 12-lead ECG's, stress ECG or Holter suggesting that non-invasive investigative methods for symptomatic patients are effective in identifying most patients who require pacing.

In our setting of a low- to middle-income country with resource limitations and the significant relationship of symptoms with requiring pacing, we feel it is reasonable to insert a PPM for symptomatic patients without routinely proceeding to EPS, if no other cause for the symptoms is identified. This strategy may result in some patients receiving an unnecessary PPM and/or higher recurrence rates of syncope or presyncope. Nonetheless, it will assist with effective resource allocation rather than investigating every symptomatic patient with EPS and/or ILR and then possibly inserting a PPM. We agree with current guidelines that asymptomatic patients likely do not require further investigation with EPS and/or ILR, as the risk of developing an indication for pacing is low. Only 4 (3%) of initially asymptomatic patients in our cohort required pacing during the 10-year follow-up, of whom only 2 (2%) remained asymptomatic at the time of requiring pacing. Future studies assessing syncopal recurrence in our setting for symptomatic patients with BFB managed with PPM insertion would be valuable.

This study aimed to identify relationships between clinical variables and mortality and/or progression of the conduction disease leading to PPM insertion in patients with BFB. DM ($p = 0.04$) and a reduced LVEF ($p = 0.05$) at diagnosis had the most significant relationship with mortality. Hypertension and advanced age were also significant contributors. The presence of symptoms ($p \leq 0.01$), either at diagnosis or later, had a significant relationship with requiring pacing, and PR interval prolongation was also associated with requiring pacing at a lower level of

significance. Potential targets for improving mortality outcomes in patients with BFB require further study. PPM insertion for symptomatic patients may be a reasonable management strategy for symptom relief (if no other symptom cause is identified) rather than following the recommended investigative algorithm for every symptomatic patient in a resource-limited setting.

Study limitations

As this was a descriptive, observational study conducted via retrospective review, the main limitation is that of all such studies, including missing data and bias. The long follow-up period of up to 10 years allowed for all patients who reached at least one of the endpoints to likely be captured. The limited cohort size and subsequent small number of patients who reached 1 of the endpoints limit comparisons of variables and the identification of significant relationships. However, to our knowledge, this is the first study in Africa to assess the relationships between clinical parameters and the need for pacing or mortality in patients with BFB. Further studies with larger cohorts are needed to properly assess and corroborate our findings.

CONCLUSION

This study identified DM and a reduced LVEF at diagnosis as the clinical parameters that relate significantly to mortality in patients with BFB, alongside age and hypertension, which were also associated at a lower level of significance. The presence of symptoms and a prolonged PR interval were the only significant variables for requiring pacing. For asymptomatic patients, further investigation is not required due to the low risk of progressive conduction defects. Extensive investigations, as per guidelines, for symptomatic patients with BFB can help reduce unnecessary PPM insertion; however, it may be challenging in resource-limited settings. Therefore, PPM insertion is a feasible alternative if no other cause is identified in such patients. Larger prospective studies with prediction models are needed to identify true predictors of mortality and requiring a PPM in patients with BFB. Further studies should be conducted to identify potential targets for reducing mortality risks.

Conflict of interest: none declared.

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