



Research Article

Transcatheter Edge-to-Edge Repair among Palestinians and Jews in the Jerusalem District, Israel

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Abstract

Background: Palestinians in the Jerusalem district in Israel have been shown to present poorer healthcare utilization patterns and worse health outcomes in a wide variety of clinical domains. Transcatheter Edge-to-Edge Repair (TEER) for Mitral Regurgitation (MR) has been established as an alternative to surgical mitral valve in patients with prohibitive surgical risk.

Objective: This study aimed to compare the outcomes of TEER for MR among both the Palestinian and Jewish population in Jerusalem. **Methods:** A retrospective analysis of prospectively collected data in TEER registry in the Jerusalem district. We compared clinical characteristics and outcomes by ethnicity. **Results:** Our study included 324 patients who had undergone TEER, of whom 57 were Palestinian (17.59%). Palestinian patients were significantly younger (66.34 ± 10.45 years vs. 78.75 ± 9.18 years, respectively, $P < 0.001$) and tended to have more cardiovascular comorbidities and more hospital admissions in the last year. Importantly, the Palestinian patients had a higher proportion of ejection fraction $< 40\%$ (61.40% vs 41.95% , $P < 0.001$) and as more functional MR (70.18% vs 63.88% , $P = 0.36$). In addition, more Palestinians requires urgent mitral intervention (26.79% vs 11.41% , $P < 0.001$). There was no difference in major complications (and 3.51% vs 3.00% , $P = 0.83$ respectively). Although Palestinian were 10 years younger when compared with Jewish patients, mortality rates were similar (5.26% vs. 3.75% , $P = 0.59$ for 30 days and 15.69% vs. 16.10% , $P = 0.69$ for one-year, respectively). **Conclusions:** Palestinian patients in this study were younger had more comorbidities that required urgent intervention. Further clinical research is address ethnic differences and gaps in therapy.

Keywords: Mitral regurgitation; Transcatheter edge-to-edge repair; Ethnicity; Palestinians; Jewish; Jews

Background

The importance of providing health care services that are acceptable to different cultural groups is widely acknowledged. Several studies have described differences in healthcare outcomes among different ethnic groups, including the morbidity and mortality arising from various chronic diseases. Differences in socio-economic, cultural, immigration-related, and genetic factors, as well as the conscious or unconscious racial bias of health care providers, may be related to such findings [1-3].

During the last four decades, life expectancy among the Arab minority in Israel, which comprises 20% of the population, has been extended by an average of 10 years [4]. However, there is a disparity in longevity between the Arab and non-Arab (mostly Jewish) populations in Israel; Arabs live, on average, four years less than Jews [5-7].

Israeli Arabs and Jews differ in their cardiovascular risk factors. Obesity, Diabetes Mellitus (DM), and a lack of exercise were more prevalent in Arab women, whereas smoking and DM were more frequent in Arab than Jewish men [8]. Moreover, rates of death due to cardiovascular causes are higher among Israeli Arabs [9,10] than among Jews.

Since 1967, Palestinian Arabs of the Jerusalem district have had the legal status of permanent residents of Israel. This population is distinguishable from Israeli Arabs who have been citizens of the country since 1948. The Arab residents of the Jerusalem district were accorded the legal status of permanent Israeli residents with social security benefits and access to health insurance (with full national health coverage since 1995). As such, these Palestinians differ from their compatriots in the West Bank and Gaza Strip.

Mitral regurgitation (MR) is the most common valve disease and the second-most common indicator for valve surgery in the United States and Europe [11].

Surgical mitral valve repair (MVR) is the gold standard treatment for severe MR but carries a higher perioperative risk in the presence of reduced ventricular function and relevant comorbidities. Transcatheter edge-to-edge repair (TEER) has been established as an alternative to surgical MVR in patients with high or prohibitive surgical risk [12,13].

Ethnic disparities in the outcomes of intervention for mitral valve disease remain understudied. The aim of this study was to compare characteristics and outcomes of TEER for MR between the Palestinian and Jewish populations in the Jerusalem district.

Materials and Methods

Study Population

We screened all patients who underwent TEER at Hadassah Medical Center and Shaare Zedek Medical Center between January 2011 and December 2020. All patients received thorough verbal and written explanations about the procedure and signed informed consent. The institutional committee for human studies of both centers approved the study protocol (0261-18-SZMC). A multidisciplinary heart team of non-interventional cardiologists, interventional cardiologists, cardiothoracic surgeons, and anesthesiologists assessed all patients. TEER was performed in high-risk- for-surgery; symptomatic patients with grade ≥ 3 MR who remained symptomatic despite stable doses of maximally tolerated Guideline-Directed Medical Therapy (GDMT). TEER was also performed for the treatment of significant symptomatic degenerative MR, according to an FDA-approved indication.

We excluded patients with missing data on mortality. For patients who had undergone a second TEER, we included the second rather than the first procedure. We compared demography, clinical characteristics, and procedural outcomes between the Palestinian and Jewish populations in the Jerusalem district.

Echocardiographic Assessment

Transthoracic Echocardiography (TTE) was performed to evaluate MR severity and to assess suitability for the procedure. MR severity was graded using an ordinal scale (grading 0-no MR, 1+ mild MR, 2+ moderate MR, 3+ moderate to severe MR, 4+ severe MR). The etiology of MR was evaluated according to the recommendations of the European Association of Echocardiography.

Intervention

TEER was performed by the implantation of a “MitraClip” (Abbott, Abbott Park, IL, USA) or the “PASCAL” (Edwards Lifesciences, Irvine, CA, USA). Procedural success was defined as a reduction of MR to grade ≤ 2 after the implantation of at least one of the devices.

Outcomes

The main outcomes were 30 days and one-year mortality. Additional parameters of interest included a difference in the demographic and clinical characteristics of patients at presentation and at the outcome of the procedures.

Statistical Analysis

All analyses compared the Palestinian and Jewish populations of the Jerusalem district. Categorical variables are

reported as an absolute number (%), whilst differences between groups were tested using the χ^2 test. Continuous variables with normal distribution are reported as mean (\pm STD), and differences between groups were tested using the Student's t-test.

Logistic regression was used to test the primary outcome-mortality. Mortality events were analyzed by time of follow-up at one, six and 12 months.

A P value < 0.01 was considered to be significant. All analyses were performed using the IBM Statistical Package for

the Social Sciences (SPSS) Statistics 26.0 (IBM Corp., Armonk, NY, USA).

Results

The final study cohort included 324 patients; 267 Jews (82.41%) and 57 Palestinians (17.59%), from the Jerusalem district. These patients had undergone TEER for MR at Hadassah Medical Center and Shaare Zedek Medical Center between January 2011 and December 2020 (Figure 1).

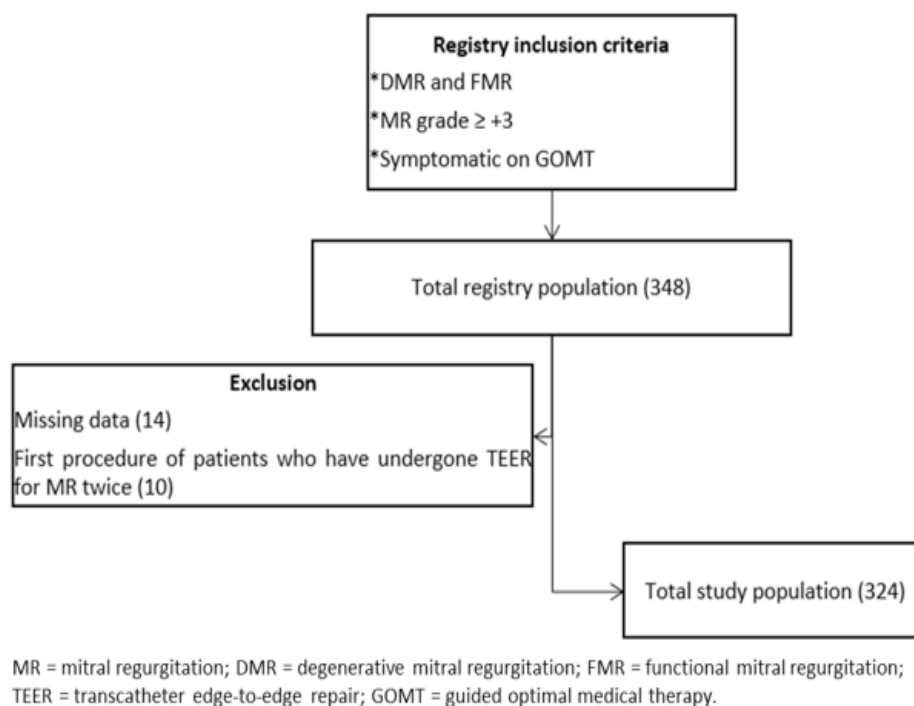


Figure 1: Study Population. MR: Mitral Regurgitation; DMR: Degenerative Mitral Regurgitation; FMR: Functional Mitral Regurgitation; TEER: Transcatheter Edge-to-Edge Repair; GOMT: Guided Optimal Medical Therapy.

Baseline characteristics by ethnicity are presented in Table 1. The most remarkable result to emerge from the data analyses was age differences. The Palestinian patients were more than 10 years younger than the Jewish patients at the time of the procedure (66.34 ± 10.45 vs. 77.75 ± 9.18 , $P < 0.001$).

Sector		Jews (N=267)	Arabs (N=57)	P value
Demographic				
Age (yr)		77.75 ± 9.18	66.34 ± 10.45	<0.001
Sex	Male – no. (%)	166 (62.17)	40 (70.18)	0.25
	Female – no. (%)	101 (37.83)	17 (29.82)	
Medical History				
Hypertension – no. (%)		241 (90.26)	50 (87.72)	0.56
Dyslipidemia – no. (%)		215 (80.52)	51 (89.47)	0.10
BMI	<25 – no. (%)	96 (39.51)	16 (30.19)	0.20
	25-35 – no. (%)	127 (52.26)	26 (49.06)	0.67
	>35 – no. (%)	20 (8.23)	11 (20.75)	<0.01
IHD – no. (%)		156 (58.43)	37 (64.91)	0.36
Previous CABG – no. (%)		64 (23.97)	19 (33.93)	0.12
Cardiomyopathy	Ischemic – no. (%)	125 (46.82)	30 (52.63)	0.42
	Non-ischemic – no. (%)	86 (32.21)	20 (35.09)	0.67
NYHA	4 – no. (%)	30 (11.41)	41 (73.21)	0.002
	Non-4 – no. (%)	233 (88.59)	15 (26.79)	
HF Hospitalization (1Y prior to procedure) – no. (%)		205 (76.78)	48 (84.21)	0.21
AF – no. (%)		136 (50.94)	34 (59.65)	0.23
DM – no. (%)		101 (37.83)	29 (50.88)	0.06
Previous CVA or TIA – no. (%)		53 (19.85)	12 (21.05)	0.83
History of Smoking – no. (%)		77 (28.84)	22 (38.60)	0.12
Pharmacotherapy				
Anticoagulants – no. (%)		132 (49.62)	29 (50.88)	0.86
Antiplatelets – no. (%)		140 (52.63)	27 (47.37)	0.47
ACEi or ARBs – no. (%)		188 (70.68)	39 (68.42)	0.73
BB – no. (%)		210 (78.65)	48 (84.21)	0.34
Loop-Diuretics – no. (%)		222 (83.46)	47 (82.46)	0.85
Echocardiography				
Mechanism of MR	DMR – no. (%)	86 (32.70)	15 (26.32)	0.34
	FMR – no. (%)	168 (63.88)	40 (70.18)	0.36
	Mixed – no. (%)	8 (3.04)	2 (3.51)	0.85
	Undefined – no. (%)	1 (0.38)	0 (0.00)	
S/P TEER for MR		6 (2.25)	4 (7.02)	0.58

Values are given as mean ± standard deviation (standard deviation; STD) or *n* (%). BMI: Body Mass Index; IHD: Ischemic Heart Disease; CABG: Coronary Artery Bypass Grafting; NYHA: New York Heart Association; HF: Heart Failure; AF: Atrial Fibrillation; DM: Diabetes Mellitus; CVA: Cerebrovascular Accident; TIA: Transient Ischemic Accident; ACEi: Angiotensin-Converting Enzyme inhibitors; ARB: Angiotensin II Receptor Blockers; MR: Mitral Regurgitation; DMR: Degenerative Mitral Regurgitation; FMR: Functional Mitral Regurgitation; EF: Ejection Fraction; S/P: Status Post; TEER: Transcatheter Edge-to-Edge Repair

Table 1: Demographic, clinical and echocardiographic characteristics at presentation.

The Palestinian patients had higher rates of cardiovascular comorbidities, including BMI >35 (20.75% vs. 8.23%, $P < 0.01$) and DM (50.88% vs. 37.83%, $P = 0.06$). They also had higher rates of dyslipidemia (89.47% vs 80.52%, $P = 0.10$), a history of smoking (38.60% vs 28.84%, $P = 0.12$), atrial fibrillation (59.65% vs 50.94%, $P = 0.23$) and a history of cerebrovascular diseases (21.05% vs 19.85%, $P = 0.83$).

Furthermore, the Palestinian patients had higher rates of IHD (64.91% vs. 58.43%, $P = 0.36$), ischemic cardiomyopathy (52.63% vs. 46.82%, $P = 0.42$), and previous coronary artery bypass surgery (33.93% vs. 23.97%, $P = 0.12$), though none of these reached statistical significance. Importantly, the Palestinian patients had a significantly lower LV function reflected by a higher rate of EF <40% (61.40% vs. 41.95%, $P < 0.01$). Moreover, there was more functional MR among the Palestinian patients (70.18% vs 63.88 %, $P = 0.36$).

Clinical and echocardiographic evaluation at presentation are presented in Figure 2. There were no differences in the medical treatment rate between the groups. However, the Palestinian patients had a higher insignificant rate of HF hospitalizations one year prior to the procedure (84.21% vs 76.78%, $P = 0.21$).

Figure 2A: EF Differences by Ethnicity

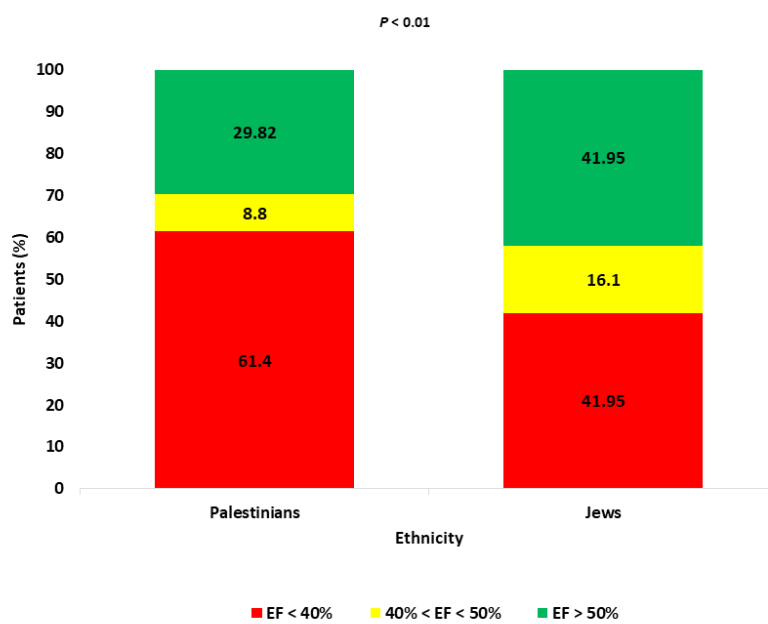


Figure 2B: Urgency Differences by Ethnicity

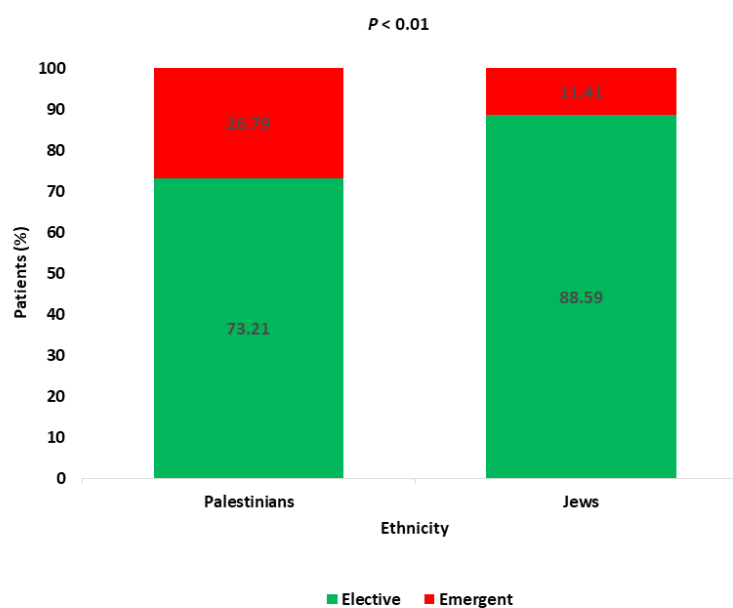


Figure 2: Clinical and echocardiographic evaluation at presentation. **(A)** Ejection Fraction (EF) at the pre-procedural echocardiographic assessment was significantly worse in Palestinians than in Jews. **(B)** Procedural urgency at admission for procedural hospitalization was significantly higher in Palestinians than in Jews.

Although both groups were treated similarly, the severity of the clinical presentation was worse among the Palestinian group; this was reflected by higher rates on urgent mitral intervention (26.79% vs 11.41 % $p < 0.001$).

The procedural characteristics and the presentation and outcomes are presented in Table 2. There was no difference in minor or major complications between the Palestinian and Jewish populations (3.51% vs 8.61%, P=0.18 and 3.51% vs 3.00%, P=0.83 respectively).

Sector		Jews (N=267)	Arabs (N=57)	P value
Periprocedural				
Hemodynamic assist	IABP – no. (%)	4 (1.50)	3 (5.26)	0.75
	Impella – no. (%)	2 (0.75)	0 (0.00)	
	ECMO – no. (%)	1 (0.37)	0 (0.00)	
Complications	Minor – no. (%)	23 (8.61)	2 (3.51)	0.18
	Major – no. (%)	8 (3.00)	2 (3.51)	0.83
Mortality				
Mortality	30D – no. (%)	10 (3.75)	3 (5.26)	0.59
	6M – no. (%)	27 (10.11)	6 (10.53)	0.92
	1Y – no. (%)	43 (16.10)	8 (15.69)	0.69
Values are given as n (%). IABP: Intra-Aortic Balloon Pump; ECMO: Extracorporeal Membrane Oxygenation.				

Table 2: Clinical characteristics and outcomes of procedure.

Interestingly, although the Palestinian patients were 10 years younger than the Jewish patients, their mortality rates were similar when compared with the Jews (5.26% vs. 3.75%, P=0.59 for 30 days and 15.69% vs. 16.10%, P=0.69 for one-year, respectively).

Discussion

Previous studies have shown an ethnic disparity regarding access to cardiac procedures in the United States. These include coronary artery bypass grafts; MVR; percutaneous coronary interventions; and advanced structural heart disease interventions such as, Transcatheter Aortic Valve Replacement (TAVR) and left atrial appendage occlusion [14,15]. However, it is not known whether there are ethnic disparities in TEER procedures and whether or not disparities have occurred in other parts of the world.

The current study showed that Palestinian patients in Jerusalem were younger when compared to the Jewish patients. They had higher rates of previous myocardial infarction and more comorbidities, as well as lower EF and more functional MR. Possible explanations for this are that lifestyle and risk factor differences exist between Jews and Palestinians.

In addition, Palestinians were more likely to present in severe clinical conditions that require urgent interventions and which could relate to less favorable outcomes. This finding could possibly be associated with the increased prevalence of comorbidities, delayed diagnosis, and/or suboptimal treatment due to poor follow-up. In the psychosocial domain, stressor effects from the Palestinian-Israeli conflict could be a contributory factor

to higher CHD mortality in Jerusalem's Palestinians [16].

Based on official Israeli cause-of-death statistics, east Jerusalem Palestinians had over double the mortality rate as a result of coronary disease when compared with the Jewish population [17].

These stressors are likely to differ in nature between the population groups and may contribute to an excess risk; this would seem to be a fertile area for further study. Furthermore, although in receipt of similar national medical insurance, the lower socio-economic status, transportation costs, inequalities in treatment, and the lower affordability of medications, could contribute to increased morbidity and subsequently lower the rates of preventive health care in ethnic minorities; this may ultimately result in fewer referrals for TEER [14].

A portion of the treatment gap may have been driven by a lack of readily accessible advanced structural heart disease centers, as well as differences in the willingness to undergo invasive or surgical procedures in racial minority patients [18]. Non-recognition of symptoms and/or new technologies by either the patient or the physician may also impact this gap [19].

Several studies reported ethnic disparities in the presentation and outcome of cardiovascular diseases [20,21] and patient access to treatment has not been equally distributed [22,23].

Specifically, prior studies in the United States have found that black individuals are less likely to receive access to costly interventional cardiovascular therapies, namely; percutaneous

coronary intervention, coronary artery bypass grafting, cardiac transplantation, ventricular assist devices, or automatic implantable cardioverters-defibrillators. Before the introduction of TAVR, black patients were significantly less likely to receive aortic valve replacement when compared with white patients [24].

A recent review of the Society of Thoracic Surgeons Transcatheter Valve Therapy (STS TVT) Registry covering the post-TAVR introduction period from 2011 to 2016, showed an underrepresentation of black individuals among those receiving transcatheter therapies [25].

Other studies covering the post-TAVR introduction period described in a recent review by Wilson et al, have also shown that black patients are underrepresented and less likely to receive AVR [26].

Two recent large cohort studies by Alkhouli, et al. both covering the period 2011 to 2016 and both using the National Inpatient Sample database and TVT Registry, showed lower rates of TAVR utilization among black patients [27-28]. The Association of Black Cardiologists examined the barriers in accepting invasive valvular treatment and found that unfamiliarity with the procedure was one of the largest contributing factors [29]. The possible solutions to this include improved patient outreach and education as well as the education of family members and caregivers who are more likely to be involved in the decision-making process of minority patients [30].

Our study identified disparities in the treatment of TEER in Palestinian patients when compared with Jewish patients; this highlights that gaps in treatment are still likely to exist, even with the upward trend in the number of TEER procedures performed.

These findings, which require confirmation, point to directions for future work to gain a better understanding of the determinants related to the outcomes of the TEER procedure, as well as to stimulate preventive action in the Palestinian population.

Targeted efforts may help address issues of under treatment for all populations but, most notably, underrepresented racial and ethnic groups. Improvements in screening protocols that encourage earlier diagnosis, as well as the implementation of patient and provider education programs should also help.

Limitations

Several limitations of our study merit consideration. First, the study is a retrospective analysis of collected data from two medical centers in Jerusalem, representing a relatively small cohort of patients; however, TEER is only available in these centers that provide therapy for the Jerusalem district. Second, due to the limited numbers of patients, some of our analysis may be underpowered to allocate significant differences in outcomes between the groups.

Third, we relied on patients' medical records to identify racial background, which may or may not correspond to the patient's self-designation. Fourth, this study does not contain granular patient-level data, such as additional clinical (NT-Pro-BNP) and echocardiographic data. Lastly, despite the desire to present the major characteristics of the groups, other clinical parameters and echocardiographic findings may impact the outcomes.

Conclusions

Palestinian patients were younger when compared with the Jewish patients. They had higher rates of previous myocardial infarction and more CVD comorbidities; in addition, more of these conditions required urgent intervention. Further clinical research is needed to establish our findings and address the ethnic differences and gaps in therapy.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki. The protocols of this study were approved by the Ethical Committee of the Hebrew University, Israel (protocol number 0072-18).

Data Availability Statement

The data that supports the findings of this study is available from the corresponding author, M.S, upon reasonable request.

Conflicts of Interest

M.S is a proctor and consultant for Abbott and Edwards Lifesciences; other authors declare no conflict of interest.

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