Clinical and Echocardiographic Trends in Percutaneous Balloon Mitral Valvuloplasty

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Research article

Keywords: Mitral Valve Stenosis, Rheumatic Heart Disease, Balloon Valvuloplasty, Echocardiography, Cardiac Catheterization

Posted Date: December 21st, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-131040/v1>

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Version of Record: A version of this preprint was published at Journal of Cardiothoracic Surgery on April 1st, 2021. See the published version at <https://doi.org/10.1186/s13019-021-01442-w>.

Abstract

Background

Percutaneous balloon mitral valvuloplasty (PBMV) is the current standard of care for selected patients with rheumatic mitral stenosis. We examined trends in patient demographics, Wilkins score and additional echocardiographic characteristics, success rates, and complications over a 30-year period.

Methods

We conducted a retrospective observational descriptive study. The study population consists of patients hospitalized in intensive cardiac care (ICCU) due to significant symptomatic MS, from January 1990 to May 2019.

Results

417 patients who underwent PBMV were eligible. Age did not change significantly over time. Male patients who were smoking and had multiple comorbidities such as hypertension, dyslipidemia, ischemic heart disease, and chronic kidney disease became more prevalence ($p=0.02$, $p=0.02$, $p=0.001$, $p=0.01$, $p=0.02$, and $p=0.001$ respectively). Wilkins score and all its components increased over time, which was higher in females ($p=0.01$), and was not correlated with age ($p=0.95$). Severe leaflets immobility (Grade 4) predicted complications ($p=0.03$, respectively). Wilkins over 9 successfully predicted the occurrence of complications, conversely, no efficient cutoff was found in the following decades. Wilkins score managed to predict a technically successful procedure ($p=0.02$), but not complications ($p=0.12$). Lastly, complication rates did not significantly change over the years.

Conclusion

Our research covers three decades of experience in PBMV and shows several trends: We see more male patients, who have multiple comorbidities. The Wilkins score increased over the years and was predictive of successful operations as opposed to complications who were predicted mainly by the leaflet mobility index.

1. Introduction

Rheumatic heart disease (RHD) is a serious cardiac complication of an immune-mediated infectious disease known as rheumatic fever that is caused by *Streptococcus pyogenes* infection in childhood. The most prominent late manifestation of RHD is valvular dysfunction, which primarily affects the mitral and aortic valves. The inflammatory process leads to a significant thickening and calcification of the valves and subvalvular apparatus and results in stenotic and/or insufficient leaflet function.^{1–3}

Percutaneous balloon mitral valvuloplasty (PBMV) was first introduced in the early 1980s by Kanji Inoue, a Japanese surgeon. He conceived the idea that a narrowed pliable valve could be expanded by splitting

the valve commissures using a balloon inflated with high pressure. Before the advent of PBMV, the recommended treatment approach for severe symptomatic narrowing of the mitral valve was surgery (i.e., surgical commissurotomy).^{4,5}

Over the years, PBMV has been extensively studied and demonstrates a high success rate and low incidence of complications, compared with the surgical approach.^{6–10}

The valve and subvalvular mechanism must be elastic and free of calcifications for PBMV to be feasible; before PBMV, these conditions are evaluated using several echocardiographic indices. The most common and recommended measure is the Wilkins score, which includes four main key criteria: mobility, thickness, and calcification of the mitral leaflets and involvement of the subvalvular mechanism. Each measure is scored from one to four according to its severity. A total score of eight or less in a patient with symptomatic mitral stenosis (MS) and nonsignificant mitral insufficiency predicts good results and a low complication rate. A total score greater than eight, especially when the mitral valve insufficiency is more than moderate, predicts a low success rate and a high complication rate, compared with the surgical approach.^{11–14} Considering this experience, the American Cardiology Association (ACC) and the American Heart Association (AHA) recommended PBMV for the treatment of patients with pliable rheumatic MS.¹⁵

The purpose of this study is to examine trends in PBMV procedures over the years during three decades, investigate complications and success rates, Wilkins score components, and relevance over time, and analyze the changes in patients' characteristics.

1.1 Rationale of the study

Our institute has been performing Percutaneous balloon mitral valvuloplasty (PBMV) for significant mitral valve stenosis for almost three decades. PBMV is the treatment of choice provided that valvular morphology is favorable. The aim of the study was to examine whether the constant decline in the incidence of RHD in the western world is also accompanied by clinical and echocardiographic changes which may affect treatment efficacy and outcome.

2. Material & Methods

2.1 Planning of the research

We designed a retrospective observational descriptive cohort study conducted at our intensive cardiac care center. The study population included patients who hospitalized significant symptomatic MS from January 1990 to May 2019. The patient's medical information was collected from the hospital's computer systems and Clalit health data service; Orion, Ofek, and Chameleon (Fig. 1).

Patients with mitral valve area $> 1.5 \text{ cm}^2$, moderate or severe mitral insufficiency, evidence of a clot in the left atrium, severe concomitant valvular disease or patients requiring bypass surgery were excluded from

the study (Table 1s. Criteria for inclusion and exclusion from the study. Supplementary). Patients eligible for the study were divided according to three decades: 1990–1999, 2000–2009, and 2010–2019. Patients were followed to evaluate disease progression.

Table 1
Patient characteristics during the study period (N = 417). Cochran-Armitage test for trend

Patient characteristics	1990–1999 (N = 165)	2000–2009 (N = 182)	2010–2019 (N = 70)	P-value (test trend)	Age adjusted
Age (Mean $\pm$ SD years) (Median; range)	57.7 $\pm$ 10.8 (57; 28–84)	55.3 $\pm$ 11.0 (56; 23–88)	55.1 $\pm$ 11.3 (54; 29–80)	.05	—
Sex (female)	139 (84.2)	147 (80.8)	48 (69.6)	.02	.02
Obesity (BMI > 30)	79 (48.2)	71 (39.2)	29 (41.4)	.19	.27
Smoking	48 (29.8)	68 (37.8)	37 (52.9)	.001	.001
Hypertension	66 (40.5)	81 (45.3)	38 (54.3)	.06	.02
Dyslipidemia	69 (42.1)	80 (45.2)	40 (58.0)	.04	.02
Diabetes mellitus	44 (27.0)	43 (24.2)	22 (31.1)	.64	.11
Chronic kidney failure	22 (13.6)	26 (14.7)	24 (34.8)	.001	.001
Ischemic heart disease	45 (27.6)	49 (27.7)	28 (40.6)	.10	.01
CABG	7 (4.3)	10 (5.6)	6 (9.0)	.19	.20
Atrial fibrillation	79 (48.2)	92 (50.5)	40 (57.1)	.24	.63
Stroke	21 (13.0)	26 (14.4)	10 (14.7)	.68	.74
Endocarditis	6 (3.8)	3 (1.7)	1 (1.5)	.21	.27
CABG; coronary artery bypass graft					

The main objective of this study was to examine trends over time regarding patient demographics, echocardiographic features of the valves and sub-valvular apparatus, success rates, and complications.

The primary end point was the procedural success rate, defined as the dilatation of the mitral valve area (MVA) to 1.5 cm² or more (MVA $\pm$ 1.5 cm²). The study's secondary end points were complication rates, including pericardial effusion, cardiac tamponade, free wall rupture, CVA or TIA, worsening or new appearance of mitral insufficiency, and death.

2.2 Statistics

Test of trend was performed by linear regression for continuous data, the Cochran-Armitage test for categorical data, and the Jonckheere-Terpstra test for ordinal data (Wilkins subscore). Trends were adjusted for age, Bonferroni pairwise comparisons were performed to assess differences between decades. Graphs of the trend over a year were created using spline interpolation. ROC analysis was performed to determine Wilkins cutoff that would best predict complications. Logistic regression was performed to determine predictors of complications and technical successful operations. These were then adjusted for age. Multivariate prediction model was then performed using the statistically significant age-adjusted univariate predictors.

Significance was set to $p < 0.05$. All analyses were performed using SPSS (version 23, IBM Inc.).

2.3 Ethics

The study was approved by the Ethics Committee of the hospital in accordance with the Helsinki Convention No. EMC-0076-17. Informed consent was waived by the Ethics committee due to the methodology of the study and the confidentiality of patients' data.

3. Results

417 patients (334 Females; aged 23–88) underwent PBMV over the 30-year study period. The overall average patient age was 56.2 ± 11.0 years. Analysis by year revealed no significant trend in age ($p = 0.09$) (Table 1). There was a significant increase in the rates of male patients, smoking, dyslipidemia, and chronic kidney disease, this remained true after adjusting for age ($p = 0.02$, $p = 0.001$, $p = 0.02$ and $p = 0.001$, respectively). In addition, after adjusting for age - there was also an increasing trend in hypertension and ischemic heart disease ($p = 0.02$ and $p = 0.01$)

Linear regression analysis of the mean Wilkins score revealed that the Wilkins score increased on average by 1.379 per decades, and 0.151 per year, and median Wilkins increased on average by 1.295 per decade, and 0.145 per year (Fig. 2). The Jonckheere-terpstra test showed a significant trend for all Wilkins variables (calcification of leaflets, Calcification of subvalvular apparatus, mobility, and thickening) (Table 2). Wilkins score was not associated with age ($r = 0.003$, $p = 0.95$), but it was significantly higher in male patients ($p < 0.01$), with mean Wilkins 9.27 as opposed to 8.77 in females.

Table 2
Wilkins score and components over decades (N = 417).

	Decades			Jonckheere -Terpstra P-value	Pairwise Bonferroni Corrected p		
	1990– 1999 (1) (N = 166)	2000– 2009 (2) (N = 181)	2010– 2019 (3) (N = 70)		1 vs 2	1 vs 3	2 vs 3
Wilkins total	7.7 ± 1.3 (8; 4–12)	9.4 ± 1.3 (9; 5–12)	10.3 ± 1.1 (10; 7–13)	.001 ¹	.001	.001	.001
< 8	71 (42.8)	10 (5.5)	1 (1.4)	.001	.001	.001	.001
≥ 8	95 (57.2)	171 (94.5)	69 (98.6)				
< 9	124 (74.7)	43 (23.8)	4 (5.7)	.001	.001	.001	.001
≥ 9	42 (25.3)	138 (76.2)	66 (94.3)				
< 10	154 (92.8)	100 (55.4)	14 (20.0)	.001	.001	.001	.001
≥ 10	12 (7.2)	81 (44.6)	56 (80.0)				
< 11	162 (97.6)	145 (80.1)	39 (55.7)	.001	.001	.001	.001
≥ 11	4 (2.4)	36 (19.9)	31 (44.3)				
Calcification of leaflets	1.92 ± 0.80 (2; 1–4)	2.26 ± 0.84 (3; 1–4)	2.80 ± 0.75 (3; 1–4)	.001	.001	.001	.001
Calcification of subvalvular apparatus	2.05 ± 0.72 (2; 1–4)	2.27 ± 0.85 (2; 1–4)	2.60 ± 0.73 (3; 1–4)	.001	.02	.001	.009
Mobility	1.90 ± 0.77 (2; 1–4)	2.25 ± 0.64 (2; 1–4)	2.43 ± 0.71 (2; 1–4)	.001	.001	.001	.051

¹Linear regression

*Data is mean ± SD (Median; range)

Decades					Pairwise Bonferroni Corrected p		
Thickening	1.84 ± 0.81	2.60 ± 0.60	2.49 ± 0.61	.001	.001	.001	.32
	(2; 1–4)	(3; 1–4)	(2; 1–4)				
¹ Linear regression							
*Data is mean ± SD (Median; range)							

Out of the 417 patients, 200 (48.0%) had complications, 184 (44.4%) mitral regurgitations, 9 (2.2%) tamponades, 6 (1.4%) ASD, 1 (0.2%) stroke, and 7 (1.7%) required urgent surgery. The rate of complications did not change over decades. Age, hypertension, LVEF, and grade 4 Mobility predicted the occurrence of complications. After correcting for age, hypertension and LVEF were no longer predictive (p = 0.07 and p = 0.11) (Table 3).

Table 3
Patient characteristics and complications.

Patient characteristics	Complications (N = 200)	No complications (N = 217)	P- value	Age adjusted		
				OR	P- value	OR
Age (Mean $\pm$ SD years)	57.5 $\pm$ 10.2	55.0 $\pm$ 11.7	.02	1.02	-	—
(Median; range)	(57; 29–84)	(55; 23–88)				
Sex	166 (49.7)	168 (50.3)	.12	1.47	.09	1.54
Female	33 (40.2)	49 (59.8)		1.00		1.00
Male						
Obesity (BMI > 30)	91 (45.7)	88 (40.7)	.31	1.23	.48	1.15
Smoking	70 (35.2)	83 (39.2)	.40	0.84	.32	0.82
Hypertension	100 (50.8)	85 (39.5)	.02	1.58	.07	1.46
Dyslipidemia	95 (48.5)	94 (43.9)	.36	1.20	.56	1.12
Diabetes mellitus	55 (28.1)	54 (25.2)	.52	1.16	.82	1.05
Chronic kidney failure	35 (17.9)	37 (17.5)	.92	1.03	.95	0.98
Ischemic heart disease	56 (28.9)	66 (30.7)	.69	0.92	.20	0.74
CABG	8 (4.1)	15 (7.0)	.21	0.57	.20	0.56
Atrial fibrillation	101 (50.5)	110 (50.9)	.93	0.98	.49	0.87
Stroke	28 (14.3)	29 (13.6)	.83	1.06	.95	1.02
Endocarditis	4 (2.1)	6 (2.9)	.61	0.72	.60	0.71
Decade			.83		.09	
1990–1999	73 (44.2)	92 (55.8)		1.00		1.00
2000–2009	98 (53.8)	84 (46.2)	.07	1.47	.06	1.51
2010–2019	29 (41.1)	41 (58.9)	.69	0.89	.75	0.91
Wilkins total	9.0 $\pm$ 1.5	8.8 $\pm$ 1.7	.12	1.10	.14	1.10
	(9; 5–12)	(9; 4–13)				

LVEF; left ventricular ejection fraction

Age adjusted						
Category	Rate	47 (57.3)	.37	1.00	.29	1.00
< 8	35 (42.7)	51 (58.0)	.31	1.29		1.02
≥ 8	37 (42.0)					
≥ 9	53 (54.1)	45 (45.9)	.08	1.42	10	1.40
10	41 (52.6)	37 (47.4)	.54	1.13	.52	1.14
11+	34 (47.9)	37 (52.1)	.34	1.25	.34	1.25
Calcification of leaflets	41 (47.7)	45 (52.3)	.72	1.00	.76	1.00
1	89 (47.1)	100 (52.9)	—	0.98	—	0.97
2	56 (51.9)	52 (48.1)	.92	1.16	.89	1.14
3	14 (41.2)	20 (58.8)	.62	0.75	.66	0.76
4			.49		.50	
Calcification of subvalvular apparatus	33 (45.8)	39 (54.2)	.80	1.00	.79	1.00
1	93 (47.0)	105 (53.0)	—	1.06	—	1.11
2	63 (51.2)	60 (48.8)	.84	1.28	.72	1.33
3	11 (45.8)	13 (54.2)	.40	1.00	.34	1.09
4			> .99		.86	
Mobility	28 (39.4)	43 (60.6)	.06	1.00	.11	1.00
1	117 (50.6)	114 (49.4)	—	1.50	—	1.46
2	44 (44.4)	56 (55.6)	.14	1.17	.18	1.09
3	11 (73.3)	4 (26.7)	.62	4.03	.79	3.83
4			.03		.04	
Thickening	27 (39.7)	41 (60.3)	.28	1.00	0.30	1.00
1	85 (47.0)	96 (53.0)	—	1.34	—	1.37
2	81 (53.6)	70 (46.4)	.31	1.71	.29	1.73
3	7 (41.2)	10 (58.8)	.07	1.04	.07	1.16
4			.95		.78	
ECHO characteristics						
LVEF; left ventricular ejection fraction						

Age adjusted					
LVEF	58.0 ± 4.7	58.9 ± 4.2	.03	0.11	0.96
	(60; 45–83)	(60; 40–72)			
Other characteristics			NS		
LVEF; left ventricular ejection fraction					

Table 4
Patient characteristics and technically successful operations.

Patient characteristics	Age adjusted					
	Successful (N = 389)	Not successful (N = 27)	P- value	OR	P- value	OR
Age (Mean $\pm$ SD years) (Median; range)	56.4 $\pm$ 11.0 (56; 23–88)	52.8 $\pm$ 10.0 (52; 36–76)	.10	1.03	–	—
Sex	313 (94.0)	20 (6.0)	.40	1.46	.38	
Female	75 (91.5)	7 (8.5)		1.00		
Male						
Obesity (BMI > 30)	166 (93.3)	12 (6.7)	.88	0.94	.70	
Yes	221 (93.6)	15 (6.4)		1.00		
No						
Smoking	144 (94.1)	9 (5.9)	.77	1.13	.85	
Hypertension	168 (90.8)	17 (7.2)	.052	0.46	.02	0.38
Yes	221 (95.6)	10 (4.4)		1.00		1.00
No						
Dyslipidemia	177 (93.7)	12 (6.3)	.85	1.08	.93	
Diabetes mellitus	100 (92.6)	8 (7.4)	.60	0.80	.41	
Chronic kidney failure	67 (93.1)	5 (6.9)	.91	0.94	.85	
Ischemic heart disease	111 (91.0)	11 (9.0)	.20	0.60	.05	
CABG	21 (91.3)	2 (8.7)	.69	0.74	.69	
Atrial fibrillation	194 (91.9)	17 (8.1)	.19	0.59	.10	
Stroke	52 (92.9)	4 (7.1)	.86	0.91	.79	
Endocarditis	9 (90.0)	1 (10.0)	.67	0.64	.67	
Decade			.01		.02	
1990–1999	159 (97.0)	5 (3.0)		1.00		1.00
2000–2009	170 (93.4)	12 (6.6)	.32	0.45	.18	0.48

LVEF; left ventricular ejection fraction, MVA; Mitral valve area

Age adjusted						
2010–2019	60 (85.7)	10 (14.3)	.007	0.19	.005	0.20
Wilkins total	8.8 ± 1.5 (9; 5–13)	10.0 ± 2.4 (9; 4–12)	.001	0.60	.001	0.61
Category	Rate	5 (6.2)	.90	1.00	.89	1.00
< 8	76 (93.8)	22 (6.6)		0.94		0.93
≥ 8	313 (93.4)					
< 9	163 (96.4)	6 (3.6)	.04	1.00	.05	1.00
≥ 9	226 (91.5)	21 (8.5)		0.40		0.39
< 10	257(96.3)	10 (3.7)	.002	1.00	.004	1.00
≥ 10	132 (88.6)	17 (11.4)		0.30		0.30
Calcification of leaflets	82 (95.3)	4 (4.7)	.25	1.00	.28	1.00
1	176 (93.6)	12 (6.4)	–	0.72	–	0.70
2	102 (94.4)	6 (5.6)	.57	0.83	.54	0.81
3	29 (85.3)	5 (14.7)	.79	0.28	.75	0.29
4			.08		.08	
Calcification of subvalvular apparatus	68 (95.8)	3 (4.2)	.001	1.00	.001	1.00
1	189 (95.5)	9 (4.5)	–	0.93	–	0.97
2	117 (95.1)	6 (4.9)	.90	0.86	.96	0.87
3	15 (62.5)	9 (37.5)	.82	0.07	.85	0.08
4			.001		.001	
Mobility	68 (95.8)	3 (4.2)	.55	1.00	.48	1.00
1	216 (93.9)	14 (6.1)	–	0.68	–	0.66
2	92 (92.0)	8 (8.0)	.59	0.51	.52	0.47
3	13 (86.7)	2 (13.3)	.34	0.29	.26	0.27
4			.20		.17	

LVEF; left ventricular ejection fraction, MVA; Mitral valve area

				Age adjusted		
Thickening	65 (95.6)	3 (4.4)	.30	1.00	.40	1.00
1	168 (93.3)	12 (6.7)	–	0.65	–	0.66
2	142 (94.0)	9 (6.0)	.51	0.73	.53	0.74
3	14 (82.4)	3 (17.6)	.66	0.22	.65	0.25
4			.08		.11	
ECHO characteristics						
LVEF	58.5 ± 4.5 (60; 50–60)	58.2 ± 3.7 (60; 50–60)	.79	1.01	.71	1.02
Pressure gradients over MV	14.73 ± 6.24 (14; 3–60)	12.74 ± 7.29 (12; 5–36)	.02	1.06	.06	1.09
MVA	1.59 ± 0.25 (1.6; 0.7–2.5)	1.38 ± 0.05 (1.4; 1.3–1.5)	.001	115.5	.001	109.4
LVEF; left ventricular ejection fraction, MVA; Mitral valve area						

In the first decade, Wilkins score with a cutoff of 9 ($< 9 / \geq 9$) was a significant predictor of complications, even after adjusting for age ($\chi^2 = 5.31$, $p = 0.02$). There were no significant cutoffs in the second or third decade. Decade ROC analysis curve revealed no significant Wilkins cutoff points. However, Wilkins score did seem to predict a technically successful procedure ($p = 0.02$).

Hypertension decreased the odds of a technically successful operation after adjusting for age ($p = 0.02$). Wilkins 9 plus or 10 plus also predicted a technically successful operation ($p = 0.04$ and $p = 0.002$, respectively). This remained true after adjusting for age ($p = 0.05$ and $p = 0.004$, respectively). In addition, the third decade had significantly lower technically successful operations compared to the first decade. (Fig. 3). Multivariate logistic regression analysis revealed that after adjusting for age, decade ($p = 0.02$) and hypertension ($p = 0.02$) were significant predictors of a technically successful operation while Wilkins 9 or higher, or 10 or higher were not significant ($p = 0.74$, and $p = 0.22$ respectively).

4. Discussion

Changes and trends in patient characteristics and in valve morphology over time may be an integral part of the declining trend in the incidence of disease that has occurred in all developed countries throughout

the world. Over time we see more male patients, with age not significantly changing. These patients present with a higher incidence of comorbidities over time, namely, smoking, hypertension, dyslipidemia, chronic kidney disease, and ischemic heart disease. In addition, more complex and less favorable valve morphology with increasing Wilkins score and its components. The aforementioned could be attributed to PBMV procedures becoming more difficult with time. In our estimation, those trends could derive from the sex change over time, and due to the unique morphological patterns of MS progression, such as pronounced leaflet calcification, which changes the onset of symptoms and consequently the preconditions for a successful procedure. These can explain, in part, why the rate of successful operations decreased significantly in the third decade relatively to the first decade.

We believe that our growing experience and a more meticulous selection of patients have led us to a stable, nonincreasing excess mortality or morbidity. We presume that the absence of any increase in complication rates is also explained by the development of the PBMV technique over the years—that is, from the use of the balloon-over-the-wire technique to the Inoue-balloon-catheter system, which enables easier maneuvering, gradual balloon expansion, and the absence of a stiff guide wire, leading to a higher incidence of left ventricle rupture.

4.1 Limitations Of Study

This study included prospective data collection and a retrospective analysis of research that began more than 20 years ago. The data analysis was based on the results of echocardiographic tests carried out in our institute and inserted into the hospital's computer system. Due to technical limitations, we have limited ability to reevaluate these measurements. Patient medical data regarding hospitalizations and visits to medical centers in our region were loaded on a 'Clalit' database several years after the initiation of the first PBMV procedures. It is possible that certain data of PBMV surgery performed at another medical center or MVR surgery that were not coordinated with our center, were missing. We estimated an uncertainty rate of missing data of no more than three percent. This rate, in our analysis, does not change the results and conclusions of the study.

5. Conclusions

As the economy developed, the incidence of rheumatic heart disease significantly decreased in developed countries. Our center serves as a national PBMV center, and in recent decades we have witnessed changes and trends in patient characteristics and valve morphology that have resulted in a decrease in PBMV success rates, while complication rates were stable. Our study revealed several trends over time, with more male patients and higher rates of certain comorbidities. We also found a steady increase in Wilkins score, yet showed it was not able to properly predict complications, rather only technically successful procedures. The occurrence of complications was mainly predicted and affected by patients' age and no or minimal forward movement of leaflets in diastole (Mobility assessment grade 4).

Declarations

1. Ethics approval and consent to participate - The study was approved by the Ethics Committee of the hospital in accordance with the Helsinki Convention No. EMC-0076-17.
2. Consent for publication - Informed consent was waived by the Ethics committee due to the methodology of the study and the confidentiality of the patients' data.
3. Availability of data and materials – All data will be available upon acceptance of request to the corresponding author.
4. Competing interests - The authors report no relationship that could be construed as a conflict of interest
5. Funding - This research did not receive any specific grants from funding agencies in the public, commercial, or not-for-profit sectors
6. Authors' contributions - O.K. and A.I. conceived of the presented idea and developed the theory. N.D and O.K collected the data, O.K and A.I performed data analysis. O.K, E.R, Y.T. verified the analytical methods. and supervised the findings of this work. All authors discussed the results and contributed to the final manuscript.
7. Acknowledgements – None.

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Figures

Figure 1

Study design.

Figure 2

Yearly median Wilkins Score.

Figure 3

Yearly rate of successful operations