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Outcomes of Non-Teflon Pledged Suture Versus Teflon Pledged Suture in Aortic Valve Replacement

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Abstract

The Teflon pledged suture approach has been considered a standard surgical aortic valve replacement (AVR) technique. Discussions are ongoing about the possibility of the non-Teflon pledged approach with superior hemodynamic and structural parameters. Our research aims to evaluate the efficacy of the non-Teflon pledged versus pledged suture technique in AVR. The non-Teflon pledged group (Group A) included 72 patients (48 %), and the Teflon pledged group (Group B) included 79 patients (52%). Our results were comparable regarding baseline demographic characteristics and comorbidities. Our results showed a significantly larger Aortic valve (AV) size in group A versus group B, and the number of sutures was significantly larger in group A versus group B. Aortic paravalvular leakage (PVL) was comparable in both groups; it was detected in three cases in group A versus two in group B. The non-Teflon pledged suture technique presents an equal alternative to the conventional Use of Teflon pledged sutures throughout aortic valve replacement. The incidence of major PVL and operational outcomes are clinically equivalent for both techniques. Teflon nonpledged suture technique provides a significant increase in AV size which improves the prognosis of AVR.

Keywords: Teflon, suture, aortic valve replacement

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1. Introduction

AVR has a 30-day mortality rate of 3.4% and a risk of vascular complications of 3.2%. That's why AVR is considered the gold standard management technique for severe AV diseases [1-3]. During AVR, the interrupted suturing technique is typically used to attach the prosthetic valve. These sutures are positioned beneath the aortic annular ring. For patients having fragile, loose tissue within their aortic ring, the pledget suture approach offers extra strength [2]. Pledget sutures provide additional support, which can delay the development of paravalvular leaks (PVLs) or aortic regurgitation [4]. After AVR, PVLs usually have a benign course. However, in their moderate to severe clinical forms, PVLs can significantly increase the possibility of postoperative mortality [5-7]. Pledget sutures should still be used with care because they raise the possibility of aortic calcification, pannus development, endocarditis, and decreased effective orifice area (EOA) [8, 9]. Because of these complications, the interrupted-nonpledget suturing approach has been considered in AVR, particularly in young cases that do not require significant support from the valve. The nonpledget suture approach reduces prosthesis-patient mismatch (PPM) and increases (EOA) after implantation. PPM describes the disproportion between the implanted valve (EOA) and the body size of patients, which can have a major effect on the patient's long-term mortality & cardiac outcomes [10, 11]. Also, interrupted sutures theoretically increase the available orifice for flowing in the outflow tract of the left ventricle. Avoiding the usage of pledgets may facilitate reoperations in the future. The differences in design and usability between pledget and no pledged suture techniques impact their clinical outcomes in AVR [12]. This study attempts to evaluate the efficiency of the non-Teflon pledged suture technique versus the Teflon pledged suture in AVR, as well as their effect on paravalvular leak occurrence and valve size.

2. Materials and Methods:

This randomized prospective study included 151 patients with surgical AVR procedures using Teflon-pledged or horizontal non-pledged methods. It was carried out from 2018 to 2023 in the Department of Cardio-thoracic Surgery, Faculty of Medicine, X University. The risk of Aortic PVL occurrence was evaluated after surgical AVR using a non-pledged suturing technique. Significant PVL may be defined as Para-prosthetic regurgitation resulting in congestive heart failure, severe hemolysis, or filling the sewing ring by more than one-third as determined by follow-up transthoracic echocardiography. Events that transpired, including PVL, within 30 days following the procedure were classified as operational mortality and morbidity. All patients aged at least 18 years with isolated AVR due to severe aortic regurge were included.

2.1 Exclusion criteria:

- Patients who were below 18 or above 70 years.
- AVR for infective causes.
- Severe Calcific AS.
- Patients with other valvular or coronary lesions, root surgeries, or LVEF< 20%.
- Patients who had major cardiac and cerebrovascular side effects.
- Patients with congenital collagen disorder.

Our study included 151 patients who met the aforementioned requirements. Patients were randomly allocated to either Group A or Group B. Group A included 72 patients who underwent horizontal non-pledged sutures, while Group B included 79 patients who had Teflon-pledged sutures applied. The same anesthesia and surgical methods were applied to all patients in both groups. Every patient received standard preoperative testing, such as an electrocardiogram, chest X-ray, and hemoglobin, electrolytes, urea, and serum creatine tests. Intraoperative trans-esophageal echocardiography and postoperative trans-thoracic echocardiography were performed six and twelve months following surgery.

2.2 Surgical Technique:

Median full sternotomy was done for all surgical AVR cases. Cardiopulmonary bypass (CPB) was carried out either via the bicaval technique or through the right atrium and distal ascending aorta. Under mild systemic hypothermia (30°C–35°C), the protection of myocardial tissue was accomplished by infusion or antegrade blood cardioplegia, cold crystalloid cardioplegia, or del Nido cardioplegia. The natural aortic valve leaflet was carefully cut and removed from the damaged annulus. Using two 2-0 needles for both techniques, ethibond sutures were inserted into the prosthetic valve's sewing ring from the left ventricle (LV) via the aortic side of the annulus. The original valve size dictated the size of the prosthetic valve. The prosthetic valve was firmly positioned on the annulus, and sutures were threaded through its sewing cuff, regardless of the suturing technique used.

2.3 Statistical analysis

We used SPSS version 27 for Windows 10. We described the quantitative data as mean and standard deviation, as they were normally distributed. The qualitative variables were expressed as frequency and percentages. We compared both groups regarding the quantitative variables by T-test (parametric) & regarding the qualitative variables by Chi-Squared/Fisher exact. A P-value less than 0.05 was reported as being significant.

3. Results and Discussion:

Both groups were comparable regarding age, sex, comorbidities, aortic valve pathology, NYHA classification, LVED, and LVEF. See Table (1) for more details. There was a significantly larger AV size in group A (21.7±1.5) versus group B (21.1±1.4) with a P- value (<0.001). The number of sutures was significantly higher in group A (17.3±1.5) versus group B (14.5±0.9). P- value (0.007). The aortic paravalvular leakage was comparable in both groups. These findings are presented in Table (2). Table (3) shows that the mechanical ventilation days, ICU, and hospital stay didn't differ significantly between both groups. Even though AVR has been used and refined over many years, surgeons still debate the best way to implant such a device. Whether to bind the prosthetic valve using pledged sutures is an intriguing topic with conflicting results in the literature due to inconsistent findings [13]. This work demonstrated similar and time-efficient outcomes using a non-Teflon pledged suture and a Teflon pledged suture technique. We noted superior outcomes among open AVR operations regarding valve size and suture numbers. Patient demographics and the risk factors of pre-operation were matched across the study groups. It is well known that valve size is a very important parameter in AVR and is often associated with high EOA and low incidence of PPM [14].

Our results showed a significantly larger AV size in group A (21.7±1.5) versus group B (21.1±1.4). Kim et al. compared pledged and nonpledged sutures. The nonpledged technique using larger valves was significantly superior in reducing PPM incidence [14]. Pledged sutures caused a moderate PPM increase [10, 14]. Similarly, Tabata et al. discovered higher EOAs in AVR patients with nonpledged sutures, particularly with 19- or 21-mm valves, compared to pledget sutures [8]. Generally, the suture approach probably didn't affect the hemodynamic result following AVR in patients whose aortic valve diameter was greater than 23 mm [14]. Regarding the drawback of using small-sized arteries, Pibarot et al. found that PPM is a very common consequence in patients with valve sizes ranging from 18 to 21 mm in diameter and that a high prevalence of PPM is coupled with poor clinical long-term outcomes [15]. Moreover, Fallon et al. proposed that any level of PPM markedly lowered long-term survival & raised readmission rates for AVR reoperation as well as heart failure. Patients with moderate or severe PPM had a considerably higher risk of readmission for heart failure and repeat AVR compared to those without PPM [16]. In contrast to our results, Qicai et al. reported that according to their preliminary experience. using the pledged suture technique led to a smooth implantation of a valve one size more than that used in the

conventional nonpledged suture technique [17]. Also, According to Nair et al., the pledged suture technique allows prostheses to be installed a size more than the largest size possible using the nonpledged suture technique [18]. The reason for this result may be because the complete valve removal and the relaxation of the contracted annulus widen the aortic annulus to some extent. Better hemodynamic performance is the outcome of this [19].

Upon studying the suture numbers, our results showed that the number of sutures was significantly more in nonpledged suture group A (17.3±1.5) versus pledged suture group B (14.5±0.9). Our results were consistent with Rasheed et al., who recorded that 71.2%of patients in the pledget group received 12–15 sutures, whereas 3.2% received 9–11 sutures, and 6.3% received 16–23 sutures, 3.2% had fewer than 12 pledget sutures, which may have contributed to the constriction of the aortic root [10]. The paravalvular leak is considered a serious complication and primary interest after AVR, regardless of the suture technique used. Clinically benign, small paravalvular leaks are frequent in the early postoperative setting and are well tolerated [20]. Our results revealed that PAL was comparable for both techniques, where PAL occurred with a percent of 4.2% & 2.5% in group A & group B, respectively. Our result is congruent with many studies that reported that no differences in PVL were found in the pledged group upon comparing it with the nonpledged group [6, 8, 13, 14, 21]. In addition, Kim et al. found that suture techniques do not affect postoperative paravalvular leakage in their study [14]. Also, LaPar et al. reported that a nonpledged suture technique is considered an equivalent alternative to the pledgets suture technique for AVR, with no increase in PVL [21].

On the contrary, Englberger et al. reported a reduction in PVL in the pledged sutures group than in the nonpledged suture group [22]. Moreover, another study by Ugur et al. showed that using pledget sutures has been suggested to decrease the risk of paravalvular leak after AVR [6]. Blackstone et al. recorded that some other studies showed that the pledged suture technique was suggested earlier to increase the risk of paravalvular leak after AVR compared to the pledget-reinforced sutures [23]. There are some controversies regarding the frequency of Paravalvular leaks in the pledged suture method of aortic valve replacement. Following our results, Laks et al.., who used the pledged suture approach, stated that the incidence of Paravalvular leak was only 2.3%. They believed that the frequency of Paravalvular leak in the pledged suture technique for AVR was low and comparable to conventional nonpledged suture techniques [24]. Englberger et al. demonstrated that pledged sutures decrease post-AVR PVL risk among 807 patients undergoing valve replacement with various techniques. Only 5.8% experienced major PVL with nonpledged sutures, affirming the advantage of pledged techniques [22]. On the other hand, Hjelms et al. stated that the total incidence of PVL was 8.8% in the eighty patients who had AVR using the pledged-suture approach; among the patients diagnosed with pure aortic insufficiency, the occurrence of PVL was increased to 26%. Therefore, they recorded that the pledged-suture technique was not appropriate for patients with pure aortic insufficiency [25].

Regarding nonpledged sutures, A lower incidence was detected in a study performed by LaPar et al., who reported that the occurrence of major PVL after AVR was uncommon (1.5%). PVL was less than 1% among patients undergoing AVR using nonpledged sutures [21]. The differences across these results may be due to the patient's clinical conditions and the impact of the associated comorbidities. Also, inclusion and exclusion criteria may affect the results. Upon investigating reoperation, our results showed that reoperation was needed in 4.2% & 5.1 in group A & group B, respectively, without a significant association between the two groups. The study by Wong et al. showed a similar result where AVR is linked to a high rate of reoperation with a percentage of 3.7% [3]. In contrast to our results, LaPar et al. reported that the reoperation rate for the paravalvular leak was extremely low, where only 0.2% of patients needed reoperation after isolated nonpledged AVR. They claimed that a nonpledged suture approach does not elevate the reoperation risk following primary AVR[21]. Similarly, Velders et al. also showed that major PVL, which requires reoperation, was found in only 0.9% of the patients. This reoperation rate for PVL is comparable to the 1% to 2% cited in the literature. It is similar to the pledged cohort rate shown in Tabata et al. and LaPar et al., which resulted in a 2% and 1.2% PVL rate, respectively [13].

The higher percentage in our study could be caused by the less strict exclusion criteria compared to previous studies. The valvular replacement may also be related to a distinctive array of complications and threats, such as PPM, recurrent AR, or infection, which may not be obvious until presenting as late mortality or morbidity necessitating reoperation. Postoperative morbidity and mortality are highly linked with the duration of CPB and ACC [26]. A formerly published study has shown that ACC time is a crucial and independent predictor of the risk of serious cardiovascular morbidities, where the risk is elevated by 1.4% for each extra minute of ACC time [27]. Aortic valve replacement postoperative morbidity can be independently predicted by ACC time. Prolonged ACC duration is linked with a considerable increase in the risks of renal failure, gastrointestinal problems, pneumonia, and multi-organ failure [26]. In our study, the results showed that no significant difference was found upon comparing cross-clamp time and cardiopulmonary bypass time between the two groups; the results were highly comparable. Our results were consistent with those of Kim et al., who stated that, in their study, no statistically significant differences were detected between the two approaches regarding the aortic cross-clamp time and cardiopulmonary bypass time [14]. Also, Ugur et al. had similar results, stating that nonpledged sutures offer an equivalent alternative to pledged sutures for AVR, with significantly decreased cross-clamp time [28]. Nevertheless, Chan et al. recorded that the aortic cross-clamp time was shorter in the nonpledged group than in the pledged group[29]. Conversely, AVR has shown that the nonpledged technique resulted in significantly shorter cardiopulmonary bypass times and aortic cross-clamp than the pledged technique [4].

Table 1: Baseline characteristics of the studied patients

Items	Group A (no=72)	Group B (no=79)	P-value
Age (mean±SD)	37.1±12.6	37.9±12.5	0.751
Sex			0.914
Male	34(47.2%)	38(48.1%)	
Female	38(52.8%)	41(51.9%)	
AV pathology			0.509
bicuspid	6(8.3%)	5(6.3%)	
quadricuspid	1(1.4%)	0(0.0%)	
tricuspid	65(90.3%)	74(93.7%)	
DM	7(9.7%)	10(12.7%)	0.569
HTN	9(12.5%)	14(17.7%)	0.372
NYHA			0.460
III	64(88.9%)	67(84.8%)	
IV	8(11.1%)	12(15.2%)	
LVED	7.0±0.6	7.1±0.5	0.411
LVEF	48.3±7.1	50.1±7.4	0.113

AV: Aortic valve; SD: Standard deviation; DM: diabetes mellitus; HTN: hypertension; NYHA: New York Heart Association; LVEF: Left ventricular ejection fraction; LVED: Left ventricular end-diastolic

Table 2: Intra-operative and postoperative outcomes of the studied patients

Items	Group A (no=72)	Group B (no=79)	P-value
CCT/minutes	57.9±7.2	57.4±6.1	0.684
Total CPB /min	83.2±9.5	82.9±9.5	0.869
No suture used	17.3±1.5	14.5±0.9	<0.001*
AV size	21.7±1.3	21.1±1.4	0.007*
Aortic PVL	3(4.2%)	2(2.5%)	0.670 (FET)
Reopening for bleeding	3(4.2%)	4(5.1%)	>0.999 (FET)

CPB: Cardiopulmonary bypass time; CCT: cross-clamp time; AV: Aortic valve; PVL: Para-valvular leak

Table 3: Outcomes of the studies in the studied patients

Items	Group A (no=72)	Group B (no=79)	P-value
MV time/hrs	6.4±2.7	6.7±2.5	0.468
ICU stay/days	2.5±0.7	2.7±0.6	0.081
Hospital stay/days	6.5±1.3	6.9±1.2	0.071

MV: Mechanical ventilation; ICU: intensive care unit

Results from LaPar et al. showed that a nonpledged technique permitted statistically shorter total cardiopulmonary bypass times and aortic cross-clamp [21]. These results may be caused by the fact that the nonpledged technique eradicates the requirement to adjust the location of pledgets and has been found to reduce the time required for cardiopulmonary bypass and cross-clamping [21]. Even though pledgets are cheap, a further cost reduction may be gained owing to these decreased times [29]. This finding is supported by Nair et al., who reported that pledged for AVR results in a shorter aortic cross-clamp time and bypass time [18]. These conflicting findings may be due to differences between surgeons, as many of them take longer to ensure a secure suture line by making more stitches and thorough suture traction. Conversely, the absence of pledges in the aorta reduces exposure to foreign material. This leads to decreased myocardial ischemic injury and shorter bypass time, thus limiting complications from extracorporeal circulation.

3.1 Limitation

The study's limitations include short follow-up and limited sample size, warranting further exploration of suture techniques' impact on long-term outcomes. Surgeon bias, potentially influenced by skill disparities, wasn't adjusted for. Variations in cardiac anesthesia and postoperative care over time posed challenges for data analysis.

4. Conclusions

With a a larger valve size and no increase in the major paravalvular leak rate, the non-Teflon pledged suture technique provides an equivalent substitute for the traditional use of Teflon pledged during open aortic valve replacement. Employing a nonpledged suture technique can make the aortic valve replacement procedure more quickly and safely.

Abbreviations

AS: aortic stenosis
AV: Aortic valve
CCT: Cross clamp time
CPB: cardiopulmonary bypass
DM: Diabetes mellitus
EOA: effective orifice area
HTN: Hypertension
ICU: Intensive care unit
LV: Left Ventricular Ejection Fraction
LVED: Left ventricular end-diastolic
LVEF: Left ventricular ejection fraction
MV: Mechanical ventilation
NYHA: New York Heart Association
PPM: prosthesis-patient mismatch
PVL: paravalvular leakage
SD: Standard deviation

Declarations

Conflicts of Interest:

The authors have no potential conflicts of interest to declare.

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Data Availability Statement: Data is released upon reasonable request from the corresponding author.

Ethics approval: This study protocol was revised and approved by the research ethics committee of the Faculty of Medicine of Beni-Suef University. The study followed the Helsinki Declaration for research ethics standards.

Consent to participate: Each person who participated in the study provided informed consent before enrolling.

Written Consent for publication

All authors read and approved the final manuscript

Code

availability NA

Authors' contributions

-Y.A.M: Corresponding Author, author, participated in data interpretation, writing and reviewing the manuscript, Conceptual design and data collection, and data analysis. E.A.M.F: Author, participated in, writing and reviewing the manuscript. Study design. A.M.G: The author participated in the design, analysis, data interpretation, writing, and reviewing of the manuscript. E.E.M.S.E: The author participated in the design, analysis, data interpretation, writing, and reviewing of the manuscript.

Competing interests

The authors declare that they have no competing interests.

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