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GLUTARALDEHYDE-TREATED AUTOLOGOUS PERICARDIUM IN AORTIC VALVE RECONSTRUCTION: AN OPTIMAL MATERIAL FOR INNOVATION TECHNIQUES. REVIEW OF THE LITERATURE

Introduction. *Reconstructive operations on the aortic valve (AV) offer several advantages over standard AV replacement with mechanical or biological prostheses. This approach has allowed patients to avoid the adverse effects of long-term antithrombotic therapy. Furthermore, it has preserved the natural mobility of the left ventricular outflow tract, resulting in improved hemodynamics across the valve. Materials for reconstruction are often readily available, making the method economically attractive.*

Problem Statement. *Autologous pericardium is the most commonly used material in AV reconstruction. Glutaraldehyde treatment of autologous pericardium (GTAP) has provided tissue with enhanced mechanical properties and reduced thrombogenicity. However, the long-term degeneration of biological tissues used in AV surgery has remained a concern despite glutaraldehyde treatment.*

Purpose. *This study has aimed to evaluate the current status and future prospects for the use of GTAP in reconstructive AV surgery.*

Materials and Methods. *A literature search has been conducted using PubMed, Web of Science, and the Google search engine. All studies on GA-fixed pericardial tissue published up to March 2023 have been identified. A total of 165 articles have been initially retrieved, of which 20 relevant studies are included in this review.*

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Results. GTAP has demonstrated excellent elasticity and surgical handling characteristics. It has enabled complex AV reconstructions with sustained immediate transvalvular hemodynamics. Degeneration and calcification rates of GTAP have been comparable to those observed in existing biological prostheses.

Conclusions. GTAP offers significant potential for advancing techniques in aortic valve pathology correction. It is cost-effective, readily available, and facilitates effective valve reconstruction. However, aggressive prophylaxis for infective endocarditis remains mandatory in the postoperative period. Further multicenter studies with larger cohorts are essential to better delineate the long-term prospects and limitations of GTAP in AV surgery.

Keywords: glutaraldehyde, biological valves, pericardium, aortic valve neocuspidization.

Autologous pericardium (AP) has played an important role in the reconstructive surgery of congenital and acquired heart malformations. Initial experience with using fresh autologous pericardium in the surgical management of aortic valve (AV) pathology has been suboptimal due to early tissue degeneration. In 1961, Love and colleagues introduced glutaraldehyde (GA)-treated autologous pericardium (GTAP) into clinical practice. GA treatment has resulted in a more stretched and compact orientation of collagen and elastic fibers in the pericardium, increasing its mechanical strength and elasticity [1].

The rate of GTAP degeneration has been significantly slower compared to fresh AP. This improvement has considerably reduced the number of complications and enhanced surgical outcomes [2].

However, GA treatment has not resolved all issues associated with the long-term degeneration of biological tissues used in heart valve surgery. This study evaluates the current status of GA treatment and future directions for preparing autologous pericardium to reconstruct the aortic valve (AV).

A literature search has been conducted using PubMed, Web of Science, and the Google search engine. The medical terms “Glutaraldehyde,” “biological valves,” “pericardium,” and “aortic valve neocuspidization” have been used. All studies of GA-fixed pericardial tissue published up to March 2023 have been identified. So far, 165 articles have been identified in the initial literature search, and 20 relevant papers have been included in this review.

The use of human AP for AV reconstruction dates back to the late 1950s. However, these initial attempts have generally been unsatisfactory due

to tissue thickening and shrinkage. Consequently, this has led to structural and functional degradation of the valve, necessitating reoperation [3].

To address the problem of tissue retraction, Love and colleagues proposed a solution in 1961, suggesting the immersion of AP in a 0.6% GA solution. Glutaraldehyde is an aldehyde organic compound with a particular affinity for proteins and reacts specifically with amine, amide, and thiol groups. GA treatment serves several purposes, such as reducing biodegradation, preserving anatomical integrity, enhancing the strength and durability of collagen fibers, rendering the tissue biocompatible, and preventing thrombosis. Tissues treated with GA retain most of the viscoelastic properties of the collagen fibrillar network [3].

The clinical outcomes of this method have been significantly better than those of fresh autologous pericardium, owing to the lower number of complications associated with tissue degeneration and retraction. Since then, GA has been widely applied in producing commercial biological valves [4].

GTAP has demonstrated excellent mechanical properties. Ozaki et al. conducted a study comparing the tensile strength of GTAP with that of natural aortic valve leaflets to evaluate its suitability for aortic valve reconstruction. The findings revealed that the ultimate tensile strength of GTAP, non-calcified leaflets, calcified leaflets, and decalcified leaflets was 10, 2.8, 1.0, and 0.8 MPa, respectively. Remarkably, GTAP exhibited a tensile strength four times higher than that of non-calcified leaflets, underscoring its suitability for aortic valve reconstruction [5].

In contrast to fresh aortic pericardium, GTAP has displayed greater density and compactness,

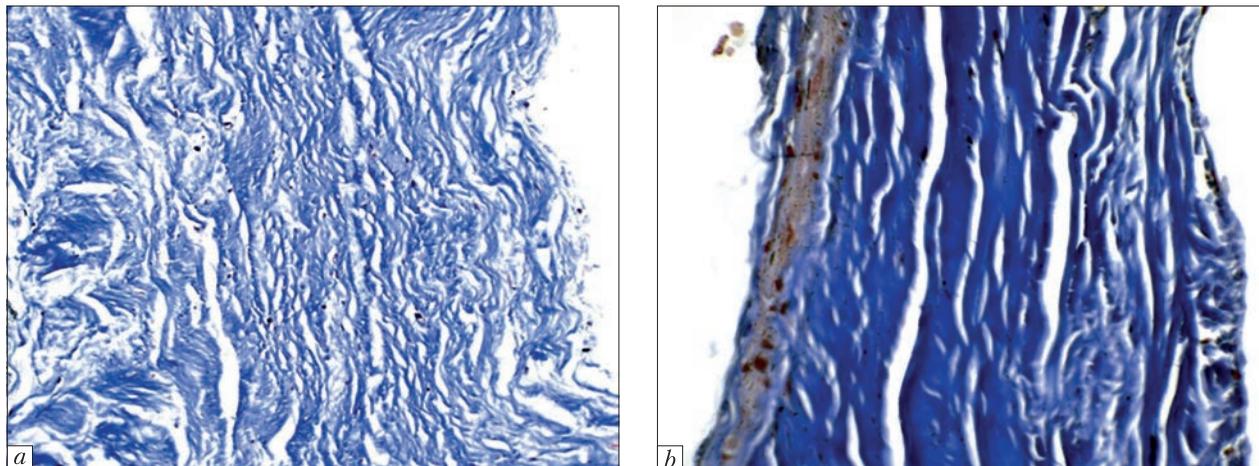


Fig. 1. Histomorphology of the human pericardial specimens stained with Masson's trichrome Magnification $\times 200$ (Own observation): *a* – Fresh human pericardium; *b* – Human pericardium, treated with 0.6% Glutaraldehyde

with reduced spacing between collagen bundles. Additionally, the collagen and elastic fibers have shifted from their typical wavy orientation to a more stretched configuration (Fig. 1, *a, b*). From a mechanical perspective, this elongation may explain the increased tensile strength of GTAP compared to native aortic valve leaflets [5].

In the morphological examination of pericardial specimens, it can be observed that the main changes after treating the pericardium with glutaraldehyde solution are localized in the fibrous layer with collagen fibers of various orientations. Masson's trichrome staining method was utilized to assess the collagen fiber condition qualitatively.

Collagen fibers within the fibrous layer of the pericardium after glutaraldehyde treatment (Fig. 1, *b*), in contrast to the untreated pericardium (Fig. 1, *a*), become more compact with a reduced distance between them. They lose their waviness and become straightened and thicker. Throughout all investigated parts of the material, collagen fibers adhere closely to each other, forming a homogeneous bundle (they become interwoven). An increase in the thickness of collagen bundles is noted. The orientation of collagen fiber bundles after glutaraldehyde treatment becomes more parallel, while in the untreated sample, collagen fi-

ber bundles are considerably more diverse in their orientation.

Despite its impact on pericardium structure and cell vitality, residual GA has not exhibited cytotoxicity toward fibroblasts. Furthermore, it has supported endothelial cell repopulation *in vitro* without any significant variations in the secretion of specific inflammatory mediators compared to a commercial bovine pericardial membrane. These findings have demonstrated that GA treatment, while altering pericardial organization and causing cell devitalization, has fostered a non-cytotoxic environment conducive to endothelialization [6].

Several advanced techniques have been proposed for reconstructing the AV using AP tissue.

Duran et al. have reported one of the most substantial experiences with total AV reconstruction using GTAP. They evaluated 92 patients divided into two groups: Group I included 27 patients who underwent AV reconstruction with bovine pericardium, while Group II consisted of 65 patients whose AV was reconstructed using GTAP. The average age of the cohort was 30 years, with a mean follow-up duration of 10.5 ± 4 years, ranging from 9 to 16 years.

For the entire cohort, freedom from reoperation rates were $68 \pm 5\%$ at ten years and $47 \pm 6\%$

at 16 years. In Group I, these rates were $68 \pm 9\%$ at ten years and $48 \pm 10\%$ at 16 years, while Group II demonstrated rates of $72 \pm 6\%$ at ten years and $45 \pm 8\%$ at 15 years.

Excluding reoperations due to Infective Endocarditis (1 in Group I and 7 in Group II) and “other” reasons, the freedom from Structural Valve Deterioration (SVD) at 10 and 16 years was $78 \pm 1\%$ and $55 \pm 10\%$ for Group I, and $80 \pm 5\%$ at 10 years and $58 \pm 9\%$ at 15 years for Group II. The mean interval to valve degeneration was 8.8 years (± 3.6 years) [7–9].

The authors have concluded that AV reconstruction with GTAP can be safely performed with excellent long-term results. However, in patients with GTAP, aggressive prophylaxis of IE has been deemed essential.

Chan et al. have presented long-term results of AV reconstruction with GTAP using the Duran technique. Their study followed 11 patients for a mean duration of 6.5 years (range: 5.3–7.7 years). At the final observation, the authors reported freedom from SVD (100%), thromboembolism (100%), IE (72.7%), calcification (100%), and reoperation (63.6%) [10].

The authors have suggested that the low immunogenicity of GTAP has contributed to slow degeneration and excellent hemodynamic performance of the reconstructed AV in the mid-term.

Urbanski et al. have assessed clinical and echocardiographic outcomes following AV reconstruction using their surgical technique, which involved enlarging the basal cusp with an autologous pericardial patch. Their study included 106 consecutive patients who underwent elective valve-sparing aortic root repair between December 2005 and June 2008. Among these, 59 patients required additional procedures on the aortic cusps, and basal cusp enlargement with GTAP was employed in 10 cases to restore the coaptation area [11].

All patients successfully underwent surgery and were discharged from the hospital after an average postoperative stay of 10 days. Echocardiography performed at discharge indicated that 7 patients had no AI, while 3 had only trivial AI.

The average coaptation height of the leaflets was measured at 9.9 ± 0.6 mm, and the mean gradient across the valve was 5.4 ± 1.9 mm Hg.

Follow-up was completed for all patients, spanning an average of 17 ± 10 months, with a range from 3 to 32 months. No events related to the valve were observed during this period. Additionally, all patients remained alive and were classified as New York Heart Association (NYHA) functional class I. The echocardiographic findings remained consistent and unchanged in all cases. Regardless of the specific technique employed for aortic root repair or the number of sinuses replaced, the method described consistently led to a significant improvement in the coaptation surface of the leaflets and produced excellent early and midterm functional outcomes [11].

The method allowed for a customized reconstruction of the aortic cusps, substantially enhancing the coaptation area. This approach is particularly beneficial for patients with aortic leaflet prolapse or constriction due to intricate aortic root and valve conditions.

Rankin et al. developed a method to calculate the form and size of the GTAP patch to reconstruct AV leaflets. Their research on aortic valve geometry suggests that the design of the leaflets should adopt a significantly more comprehensive approach than previously employed. For bicuspid valves, the recommended free-edge length is 2.25 times the annular diameter, whereas for tri-leaflet valves, it is 1.5 times the annular diameter. Accordingly, the total free-edge length of the leaflets should equal 1.5 times the valve’s circumference. They published an analysis of 2 patients whose AVs were reconstructed with this technique. The authors concluded that TEE and TTE revealed optimal leaflet mobility without residual insufficiency. Follow-up for these patients lasted two years, with TEE demonstrating excellent results [12–13].

These data have shown that GTAP is an excellent material in terms of elasticity, enabling complex reconstruction of the AV structures.

The most significant experience with the use of GTAP for AV reconstruction was published by

Ozaki et al. In 2018, Ozaki et al. reported a study that included 850 consecutive patients who underwent AV reconstruction with GTAP utilizing the original Aortic Valve Neocuspidization (AVNeo) technique (Fig. 2). The median age was 71 (range 13–90), and the mean follow-up interval was 53.7 ± 28.2 months. In-hospital mortality occurred in 16 patients. The average peak pressure gradient on the aortic valve 8 years after the operation was 15.2 ± 6.3 mm Hg. Actuarial absence of death was 85.9%, cumulative cases of reoperation were 4.2%, and moderate or greater recurrent aortic regurgitation occurred in 7.3% of cases [14–15].

Krane et al. conducted a meta-analysis comparing aortic valve replacement (AVR) using GTAP to biological valve replacement. This analysis involved 103 patients who underwent the AVNeo operation. The mean follow-up duration was 426 ± 270 days. Among the patients, 80 (77.7%) had been diagnosed with aortic stenosis, while 23 (22.3%) had aortic regurgitation. The mean age of the patients was 54.0 ± 16.4 years, with an age range spanning from 13.8 to 78.5 years. Postoperative follow-up data were available for 93.8% of the patients, and these records did not reveal any significant changes in hemodynamic parameters when compared to the measurements taken at the time of discharge. When comparing the AVNeo procedure to the virtually implanted Trifecta Bioprosthesis, it was observed that AVNeo had a notably lower mean pressure gradient (8.5 ± 3.7 mm Hg vs. 10.2 ± 2.0 mm Hg, $P < 0.001$) and a higher mean effective orifice area (2.2 ± 0.7 cm² vs. 2.1 ± 0.4 cm², $P = 0.037$) [16].

Benedetto and colleagues reported clinical and echocardiographic outcomes of 55 patients (mean age 58 ± 15 years) undergoing AVNeo with autologous pericardium in 2 UK centres from 2018 to 2020. These results were included in a meta-analytic comparison between series on AVNeo versus Trifecta, Magna Ease, Freedom Solo, Freestyle, Mitroflow, and autograft aortic valve [17].

A meta-analysis found no significant differences between AVNeo and most biological valves, except for Magna Ease, regarding structural valve

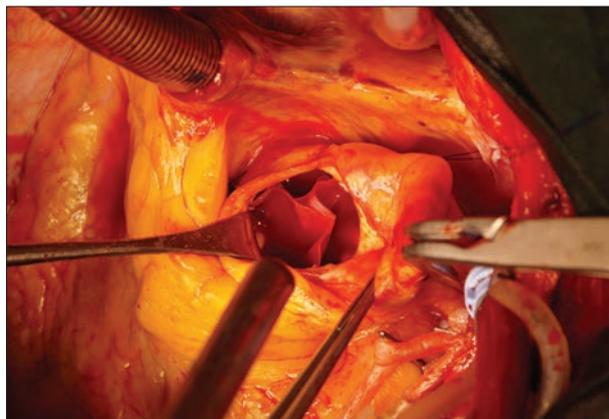


Fig. 2. AVNeo leaflets with GTAP (own observation)

deterioration, reintervention, and endocarditis. Based on available literature data, this analysis demonstrates that AVNeo using GTAP is a safe approach with excellent hemodynamic performance. Its midterm risk of valve-related events is similar to most biological valve replacements [17].

Unai et al. reported the results of an assessment of the Ozaki procedure, comparing its hemodynamic performance and durability to stented bioprosthetic valves. They divided all patients into two groups: Group 1 consisted of patients who had undergone the Ozaki procedure (776 patients), and Group 2 included patients who received stented bovine pericardial valves (627 patients). Among the matched patients, it was observed that the Ozaki group had a higher occurrence of aortic regurgitation (AR) compared to the PERIMOUNT group (severe AR at 1 and 6 years: 0.58% and 3.6% for Ozaki vs. 0.45% and 1.0% for PERIMOUNT, respectively; $P[\text{trend}] = 0.006$). However, this was associated with a steep learning curve. Conversely, the peak gradient showed the opposite trend, with values of 14 and 17 mm Hg for Ozaki and 24 and 28 mm Hg for PERIMOUNT at these time points ($P[\text{trend}] < 0.001$). Freedom from re-replacement was similar between the two groups ($P = 0.491$). The survival rate of the Ozaki cohort reached 85% at 6 years. Although patients who underwent the Ozaki procedure had lower gradients, they also experienced more recurrent aortic regur-

gitation (AR) than those receiving PERIMOUNT bioprostheses. Despite concerns about recurrent AR, the results affirm a low risk and good midterm performance of the Ozaki procedure, supporting its continued use [18].

Todurov et al. demonstrated that Ozaki concept may be used for pulmonary valve reconstruction with the GTAP and excellent hemodynamic results up to the mid-term results [19–20].

GA treatment of autopericardium allows obtaining the tissue with better mechanical properties and low thrombogenicity. GTAP demonstrates excellent characteristics in terms of elasticity and surgical handling. It permits per-

forming complex AV reconstructions with excellent immediate transvalvular hemodynamics preserved to the long term. GTAP degeneration and calcification rates are similar to most existing biological prostheses.

The material is cheap and readily available. Aggressive prophylaxis of Infective Endocarditis is mandatory in the postoperative period.

GTAP opens prospects for implementing novel techniques in correcting Aortic Valve pathology. Nevertheless, new multicentre studies with more observations are mandatory to evaluate better perspectives and limits of the use of the GTAP in AV surgery.

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АУТОЛОГІЧНИЙ ПЕРИКАРД, ОБРОБЛЕНИЙ ГЛЮТАРАЛЬДЕГІДОМ В РЕКОНСТРУКЦІЇ АОРТАЛЬНОГО КЛАПАНА: ОПТИМАЛЬНИЙ МАТЕРІАЛ ДЛЯ ІННОВАЦІЙНИХ МЕТОДИК. ОГЛЯД ЛІТЕРАТУРИ

Вступ. Реконструктивні операції на аортальному клапані (АК) мають низку переваг перед стандартною заміною його на механічний або біологічний протез. Цей метод дозволяє уникнути негативних наслідків тривалої антитромботичної терапії. Зберігається природна рухливість вихідного тракту лівого шлуночка, що забезпечує кращу гемодинаміку через клапан. Матеріали для реконструкції доступні, а метод є економічно привабливим.

Проблематика. Аутоперикард є найбільш часто використовуваним матеріалом при АК-реконструкції. Обробка аутоперикарда глютаральдегідом (ГТАП) дозволяє отримати тканину з кращими механічними властивостями та низькою тромбогенністю. Однак лікування глютаральдегідом (ГА) не вирішило всіх проблем, пов'язаних із довгостроковою дегенерацією біологічних тканин, які використовуються в хірургії АК.

Мета. Оцінювання поточного стану та майбутніх перспектив використання ГТАП у реконструкційній хірургії АК.

Матеріали й методи. Пошук літератури проводився за допомогою баз даних *PubMed* і *Web of Science*, пошукової системи *Google*. Усі дослідження перикардальної тканини, фіксованої ГА, були визначені з існуючої літератури до березня 2023 року. З виявлених 165 статей 20 відповідних було залучено до цього огляду.

Результати. ГТАП демонструє чудові характеристики з точки зору еластичності та хірургічної обробки. Це дозволяє виконувати складні АК-реконструкції з відмінною негайною трансклапанною гемодинамікою, що зберігається на тривалій термін. Швидкість дегенерації та кальцифікації ГТАП подібна до більшості існуючих біологічних протезів.

Висновки. ГТАП відкриває перспективи впровадження нових методик корекції патології аортального клапана. Аналізований матеріал дешевий і доступний. У післяопераційному періоді обов'язкова активна профілактика інфекційного ендокардиту. Проте нові багаточентрові дослідження з більшою кількістю спостережень є обов'язковими для оцінки кращих перспектив і обмежень використання ГТАП в АК хірургії.

Ключові слова: глютаровий альдегід, біологічні клапани, перикард, некуспідизація аортального клапана.