Review

Urologia Internationalis

Urol Int
DOI: 10.1159/000495513

Received: August 14, 2018
Accepted after revision: November 14, 2018
Published online: December 5, 2018

Review

Pericardium in Reconstructive Urologic Surgeries: A Systematic Review and Meta-Analysis

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Keywords

Pericardial tissue · Reconstructive urologic surgery · Penis · Urethra · Bladder · Kidney

Abstract

Introduction: The use of pericardium has been expanded into different surgical modalities; however, there are scarce data regarding the feasibility of the pericardium in reconstructive urologic surgeries. We systematically reviewed the literature on the effectiveness of the pericardial tissue for reconstructive urologic surgeries. ***Materials and Methods:*** PubMed and Scopus were searched online for evidence on the use of the pericardium in urologic surgeries. Through the methodology recommended by the Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines, 38 of 4,071 studies were identified. ***Results:*** A total of 715 patients and 139 animals underwent reconstructive urologic surgeries using the pericardium. Bladder, urethral, and renal reconstructions were successful in 100% of the human cases. The rates of dissatisfaction, glans hypoesthesia, and penile shortening were comparable between the pericardial graft surgeries and the other operations during penile straightening, but there was a trend among the patients with pericardial grafts toward having a more penile curvature at follow-up (risk ratio [RR] 2.03, 95% CI 0.90–4.61, $p = 0.09$; $I^2 = 0\%$). Among the animal studies, there were 4 reports of penile reconstruction, 7 studies of bladder reconstruction, and 1 study of urethroplasty. Bladder reconstruction and urethroplasty were successful in 83 and 20% of the animals, respectively. The pooled result of the stimulated intracorporeal pressure 5 V significantly favored pericardial grafts during penile reconstruction (RR 2.61, 95% CI 1.26–3.97, $p = 0.0002$; $I^2 = 0\%$). ***Conclusions:*** Our systematic review demonstrates the feasibility of the pericardium, regardless of its type, in urologic surgeries. It, however, seems that urethral substitution needs further investigation. Given the lower cost, easier handling, and less immunogenicity of the pericardium, further studies are required to examine its pros and cons.

Introduction

Reconstructive surgeries are performed using either flaps or grafts as substitutes for the original tissues, and these techniques have been employed in urologic surgeries for decades [1]. Reconstructive urologic surgeries are implemented in the repair of urogenital organs [2, 3].

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During reconstructive surgeries, several biomaterials and prostheses are routinely used as a substitute material. A variety of grafts including skin, bladder, colon, and buccal mucosa have been utilized in reconstructive urologic surgeries [4–6]. More recently, some other tissues such as amniotic membranes [7] and pericardial tissues have been used in reconstructive urologic surgeries [8–11].

In reconstructive surgeries, 3 main aspects should be considered, including the site of implantation, the method of implantation, and the graft harvesting and preparation method. The implementation of tissue-engineered grafts (i.e., synthetic and non-biodegradable materials) has been evolved during the past decade [12–14]. However, given the quick encrustation, susceptibility to infection, and likelihood of immunogenic reactions, new biodegradable and less immunogenic substitutes such as the pericardium, omentum, and placenta have been introduced [15, 16].

The pericardium first attracted the attention of cardiothoracic surgeons, who implemented it in a large number of cardiac defects and used it in the development of cardiac valves in patients with valvular malfunction and correction of the congenital malformations [17]. Thereafter, its use expanded into other surgical modalities – particularly general, vascular, urologic, ophthalmologic, and neurosurgical operations [18–22]. Different types of the pericardium tissue are used as a substitute in urologic surgeries; they include animal pericardium (treated bovine pericardium [BP], treated porcine pericardium, and tissue-engineered sheep pericardium) [23–25], and treated human cadaveric pericardium (HCP) [26, 27]. Despite the potential feasibility of the pericardium for the reconstruction of urogenital defects; however, it is yet to be widely implemented.

Herein, in this systematic review, we seek to provide a comprehensive overview of using the pericardial tissue in urologic surgeries. We summarize the characteristics of patients or animals, operation features, and surgical outcomes. Additionally, we meticulously discuss pericardial tissue utility – regardless of the type (human or animal) – and highlight some probable perspectives for the implementation of the pericardial tissue in urologic surgeries.

Methods

Data Sources and Search Strategy

A systematic review of electronic databases according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses was performed [28]. Two reviewers (M.A.H. and Y.R.) independently searched for evidence focusing on the use of pericardial-based grafts during urologic surgeries.

The reviewers systematically searched the PubMed and Scopus electronic databases from January 1950 to October 2016, and subsequently updated the search up to the end of April 2017. English language articles regarding the use of the pericardial tissue, regardless of preparation techniques and materials, in urologic surgeries were collected. The relevant keywords used in the search included "BP or pericardium" in combination with each of "bladder, urethra, ureter, pelvis, kidney, and penis". In addition to the electronic databases, some relevant articles found in other sources (i.e., review articles, the bibliographies of relevant studies, hand-searching of relevant journals) were also incorporated (online suppl. Table 1; for all online suppl. material, see www.karger.com/doi/10.1159/000495513).

Data Abstraction and Quality Assessment

The reviewers read the titles and abstracts of articles to find relevant articles meeting the following criteria: (1) studies using the pericardial tissue in urologic surgeries; (2) any type of pericardium (human, animal, or tissue-engineered) with any preparation method; (3) any anatomic location used in the setting of urologic surgeries; (4) human or animal studies; and (5) the availability of full-texts.

The reviewers read the full-texts of the screened articles. The main data extracted from the articles comprised the pericardial tissue type, the anatomic location of repair, the type of surgery, and the outcomes of procedures (i.e., the restoration of normal function, reoperations due to the failure of surgery defined as success rate, and any reported relevant complications or outcomes of interest relevant to surgery). The majority of the outcomes in penile reconstruction included the patients' self-reported satisfaction, glans hypoesthesia, and curvature of the penis greater than 30° whether or not it interfered with the patients' coitus, and penile shortening. In all steps of the review, discrepancies were discussed until a similar decision was reached (consultation with J.H. and S.H.). In addition, 2 reviewers independently evaluated the quality of human studies using Newcastle-Ottawa quality assessment scale [29]. There are different methodologies for the quality assessment of animal studies; therefore, we used a tool to assess the internal validity of studies by the implementation of a 5-score based criteria including 5 items: (1) sample size calculation; (2) randomization (selection bias); (3) blinding of investigator/caretaker (performance bias); (4) blinding of outcome evaluation (detection bias); and (5) reporting drop-outs (attrition bias).

Data Synthesis

Descriptive statistics was used to summarize the characteristics of the extracted studies. The continuous variables were reported as means (ranges) and the categorical ones as numbers (percentages). For meta-analysis, similar outcomes were extracted from the studies comparing pericardial tissues with other grafts/controls. All continuous and dichotomous variables were analyzed using the Mantel-Haenszel method and the inverse variance statistical method, respectively. Heterogeneity was assessed using the I^2 statistic. All variables were analyzed using the fixed-effects model in the absence of substantial heterogeneity (χ^2 test p value >0.1 and $I^2 < 50\%$); otherwise, the random-effects model was applied. The presence of publication bias was evaluated by drawing funnel plots. The causes of heterogeneity and publication bias were also evaluated using sensitivity analysis via excluding outlier studies. All statistical analyses were carried out using RevMan, version 5.3.5 (Cochrane Collaboration, Oxford, UK).

Results

Overall Studies

Our database search yielded 4,071 abstracts. All titles and abstracts were screened apropos the probability of entrance into the full-text review. Finally, 38 full-text articles were quantitatively reviewed (Fig. 1). There were 26 clinical studies on human samples [8–11, 26, 30–50] and 12 studies on animal models [23–25, 27, 51–58]. Since the outcome of interest in this review was the result of pericardial grafts in reconstructive urologic surgeries, we also entered case reports in our review. Seven hundred fifteen patients underwent surgical reconstruction using pericardial grafts and had completed follow-up evaluations; 8 of these patients were published as case reports [8, 10, 11, 31, 37, 40, 47, 48]. In addition, urologic reconstructive surgeries using pericardial grafts were performed on 139 animals comprising 45 rats [27, 54–56], 57 dogs [52, 53, 57, 58], 31 rabbits [24, 25, 51], and 6 pigs [23]. The characteristics, overall outcomes, and the quality of all studies are summarized in Tables 1 and 2.

Human Studies

Of the human studies, 20 studies reported the outcomes of penile reconstruction surgeries [9, 10, 26, 30, 32–36, 38–41, 43–47, 49, 50]. Of those, there were 16 studies on patients with Peyronie's disease and/or penile straightening [9, 26, 30, 32–36, 39, 43–47, 49, 50], 3 reports on penile prosthesis complications [10, 38, 41], and 1 case of congenital chordee of the penis [40]. There were 2 reports of urethral reconstruction with successful outcomes and no complications [37, 42]. One study reported the outcomes of urinary incontinence repair in 22 females, who underwent the urethral sling procedure with the use of BP grafts [42]. Another included a female with urinary incontinence caused by urethral diverticulum, treated via urethral reconstruction using a BP graft [37]. Elsewhere, bladder wall reconstruction using BP grafts was successfully performed in a female with an enterovesical fistula [11], and in a male with an iatrogenic bladder defect caused by irradiation [8]. There was a single successful report of kidney reconstruction using a BP graft, during which BP was successfully employed for the closure of a renal capsule following a partial nephrectomy [48]. Processed BP has also been used for the repair of a traumatized testis, which was successful at 3 months [31]. Further details of perioperative outcomes are presented in online supplementary Table 2.

The outcomes of 15 patients undergoing penile reconstruction using HCP revealed an approximately 52% success rate in 2 studies [9, 41]. Other human studies using

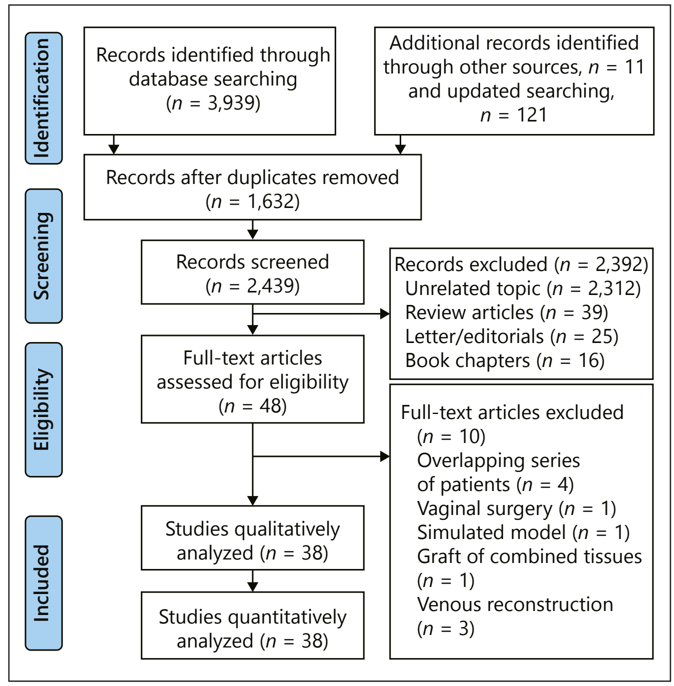

Fig. 1. Flow diagram showing the selection of studies.

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HCP compared the result of the pericardial graft with other substitutes (i.e., dermal grafts, penile remodeling, or tunica albuginea plication). There were no detailed results in 2 studies for comparing the pericardial graft with other graft materials [35, 44]. Pooled results using the fixed-effects model revealed that there were no significant differences between HCP and other substitutes regarding the rate of dissatisfaction, glans hypoesthesia, and penile shortening at the last follow-up. There was no heterogeneity among studies. In contrast, there was a trend among the patients with HCP toward having a large penile curvature at the last follow-up compared with other substitutes (risk ratio [RR] 2.03, 95% CI 0.90–4.61, $p = 0.09$; $I^2 = 0\%$; Fig. 2). There was no significant publication bias based on funnel plots (online suppl. Fig. 1). Four hundred fifty-six patients underwent penile reconstruction with BP grafts [32–34, 38, 39, 43, 45, 50]; approximately 91% (range 75–100%) of those patients were satisfied with the outcomes of surgery at last follow-up, and the mean of the success rate was approximately 98.6% (range 93.3–100%). There was a single case of penile reconstruction with a BP graft, during which the BP was used as a lining for a complicated penile prosthesis [10]. There were 2 failed procedures after penile reconstruction, consisting of the repair of congenital chordee [40], the development of an inclusion cyst, and the contraction of the HCP graft in Peyronie's disease [47].

Table 1. Characteristics and outcomes of the pericardial grafts in humans

Author	Country	Number of patients	Gender	Age, year‡, mean	Surgery type	Study groups	Setting/disease	Pericardium type	Perioperative medical therapy*	Follow-up duration, month†, mean	Overall outcomes	NOS score
Leungwattanakij et al. [9], 2001	USA	11	Male	50.5	Penile reconstruction	NA	Peyronie's disease	Tutoplast HCP	Vancomycin 1g + Levofloxacin 500 mg IV	30 (25–35)	54.5% successful	6
Chun et al. [21], 2001	USA	9	Male	59	Penile reconstruction	1 = Dermal graft harvested from the lower abdomen 2 = Tutoplast HCP graft	Peyronie's disease	Tutoplast HCP graft	Patients continued antibiotics. A dose of 5 mg diazepam was started orally at bedtime and amyl nitrite was given to prevent erection up to 1 month	6 (1–8)	88% satisfied	7
Palese et al. [41], 2001	USA	4	Male	59.5	Penile reconstruction	NA	Penile prosthesis erosion and fibrosis	Tutoplast HCP	Ancef and gentamicin IV before surgery	9.5 (6–15)	50% Successful	2
Egydio et al. [34], 2002	Brazil	33	Male	54 (31–72)	Penile reconstruction	NA	Peyronie's disease	HP Biopróteses and Fisics-Incor BP	NR	19.4 (5–30)	100% successful	4
Gulino et al. [36], 2002	Italy	4	Male	NR	Penile reconstruction	1 = Gore-Tex 2 = Alloderm 3 = BP 4 = Vein 5 = Tutoplast HCP 6 = Porcine intestine	Peyronie's disease	Tutoplast HCP	NR	12	100% successful	6
Pais et al. [40], 2002	USA	1	Male	1	Penile reconstruction	NA	Congenital chordee of the penis	Periguard BP	NR	6	Failed	–
Pelosi et al, [42], 2002	USA	22	Female	52	Urethral sling procedure	NA	Stress urinary incontinence	YAMA UroPatch BP	7 days antibiotic perioperatively	20 (9–26)	100% successful and No complications	5
Usta et al. [43], 2003	USA	30	Male	51	Penile reconstruction	1 = Tutoplast HCP graft 2 = Penile prosthesis plus penile modeling 3 = penile prosthesis plus Tutoplast HCP graft	Peyronie's disease	Tutoplast HCP graft	NR	21.9	77.4% satisfied	3
Thiel et al. [47], 2005	USA	1	Male	40	Penile reconstruction	NA	Peyronie's disease	Tutoplast HCP graft	NR	9	Failed due to inclusion cyst and graft contraction	–

Table 1. (continued)

Author	Country	Number of patients	Gender	Age, year‡, mean	Surgery type	Study groups	Setting/disease	Pericardium type	Perioperative medical therapy*	Follow-up duration, month†, mean	Overall outcomes	NOS score
Lopes et al. [10], 2007	Brazil	1	Male	62	Lining for a penile prosthesis	NA	Penile prosthesis infection	BP graft	Cefazolin 1 g/day IM for 72 h + gentamicin 80 mg/6 h for 2 days IM + Metronidazole 400 mg/8 h IV for 48 h	24	100% satisfied	–
Taylor et al. [46], 2008	USA	81	Male	54	Penile reconstruction	1 = TAP 2 = Tutoplast HCP graft	Peyronie's disease	Tutoplast HCP	Sildenafil 25 mg nightly for 40 nights	58 (6–185)	75% very satisfied or satisfied	8
Egydio et al. [32], 2008	Brazil	25	Male	55.4 (32–69)	Penile reconstruction	NA	Peyronie's disease	BP graft	NR	11.2 (3–22)	100% satisfied	7
Lopes et al. [38], 2009	Brazil	5	Male	38.4	Penile prosthesis implantation	NA	Erosion, infection, and fibrosis following the implantation of penile prosthesis	BP graft	Ceftriaxone for 2h preoperatively and 7 days postoperatively	32 (9–48)	100% satisfied	3
Gunasekaran et al. [37], 2011	USA	1	Female	44	Urethral reconstruction plus anti-incontinence procedure	NA	Giant urethral diverticulum	BP collagen matrix graft	NR		100% successful and No complications	–
Moon et al. [11], 2011	Korea	1	Female	67	Bladder reconstruction	NA	Enterovesical fistula	Supple Periguard BP	NR	30	100% successful	–
Chung et al. [30], 2011	Canada	33§	Male	54.1	Penile reconstruction	1= dermal graft 2= Tutoplast HCP graft 3= Stratasis SIS graft	Peyronie's disease	Tutoplast HCP graft	Ten patients (11.6%) received intralesional verapamil prior to graft surgery. 12 patients (14%) were using PDE5 inhibitors or intracavenous agents preoperatively	79.2	87% successful	8
Flores et al. [35], 2011	USA	52	Male	57	Penile reconstruction	1 = Tutoplast HCP graft 2 = Grafting with Surgisis	Peyronie's disease	Tutoplast HCP graft	NR	6	46% had 6-point decrease in IIEF	8
Sansalone et al. [43], 2011	Italy	157	Male	55 (29-70)	Penile reconstruction	NA	Peyronie's disease	BP	NR	20 (12–24)	100%	7
Uhlman et al. [48], 2012	USA	1	Male	NR	Bolster renal capsule after PN	NA	Renal tumor	Synovis Periguard BP	NR	NR	100% successful	–
Zucchi et al. [50], 2013	Italy	60	Male	58	Penile reconstruction	NA	Peyronie's disease	Hydrix BP collagen matrix	NR	40 (36–84)	80% satisfied	6

Table 1. (continued)

Author	Country	Number of patients	Gender	Age, year‡, mean	Surgery type	Study groups	Setting/disease	Pericardium type	Perioperative medical therapy*	Follow-up duration, month†, mean	Overall outcomes	NOS score
Egydio et al. [33], 2013	Brazil	105	Male	56.3 (32–75)	Penile reconstruction	NA	Peyronie's disease	BP graft	An intracavernous injection of 20 μg of prostaglandin E1	18.2 (6–46)	89.4% satisfied	7
Ciftci et al. [31], 2014	Turkey	1	Male	16	Testis reconstruction	NA	Testis rupture after gunshot	Tutoplast processed BP	NR	3	100% satisfied and successful without complications	–
Segal et al. [44], 2014	USA	5ǁ	Male	NR	Penile reconstruction	1 = Penile prosthesis 2 = Penile prosthesis plus straightening maneuvers	Penile straightening	NR	Postoperative antibiotics NR time	NR	NR	6
Chee et al. [8], 2015	Singapore	1	Male	47	Bladder wall reconstruction	NA	Iatrogenic defects of the bladders due to pelvic irradiation	BP graft	NR	6	100% successful	–
Otero et al. [39], 2016	Spain	43	Male	50	Penile reconstruction	NA	Peyronie's disease	Peri-guard BP	Cefazolin 2 g IV as prophylaxis plus 7 to 10 days postoperatively plus 5 mg/day of tadalafil for 3 months plus vacuum device without constricting ring for 10 min tid starting 2 weeks postoperatively for 3 months	14	100% successful and 85.5% satisfaction	5
Silva-Garreton et al. [45], 2016	Argentina	28	Male	54.9	Penile reconstruction	NA	Peyronie's disease	BP graft	NR	66.8 (2–148)	75% satisfied plus 3.5% failed due to prosthetic infection and urethrocutaneous	5

* Perioperative medical therapy in patients undergoing penile reconstructions included per-required sildenafil in addition to mentioned therapies.
† Follow-up duration is presented as mean (range).
‡ Age is presented as mean ± SD.
§ It included 33 patients undergoing HCP grafting, while only 23 patients were followed up within 5 years.
ǁ The outcomes of patients undergoing pericardial grafting could not be separated from other corporeal reconstruction (5 from 14 patients).
NOS, Newcastle – Ottawa quality assessment scale; NA, not applicable; NR, not reported; BP, bovine pericardium; IV, intravenous; HCP, human cadaveric pericardium; IM, intramuscular; IVC, inferior vena cava; TAP, tunica albuginea plication; PN, partial nephrectomy; RCC, renal cell carcinoma; SIS, small intestinal submucosa; IIEF, international index of erectile function.

Table 2. Characteristics and outcomes of the pericardial grafts in animal models

Author	Country	Number of subjects	Gender	Mean of weight, kg*	Surgery type	Study groups	Setting/disease	Pericardium type	Perioperative medical therapy	Follow-up duration, week†	Overall outcomes	NOS score
Nakazono et al. [57], 1973	USA	5 dogs	NR	– (15–20)	Bladder reconstruction	NA	Bladder wall defect	70% anhydride treated BP	1 g/day Cephaloridin for 5 days postoperatively	14–18	80% successful	0
Novick et al. [58], 1978	USA	16 dogs	Female	– (15–20)	Bladder reconstruction	1 = Control 2A = BP graft covered by omentum graft who sacrificed 1 year later 2B = Open biopsies till BP graft disappeared 3 = BP graft covered by omentum graft	Bladder wall defect and chronic contracted bladder	BP	1 g/day Cephaloridin for 7 days postoperatively	14–53	100% successful	1
Kambic et al. [52], 1992	USA	10 dogs	Male	22.5	Bladder reconstruction	1 = control 2 = partial cystectomy	Bladder augmentation	Acetic anhydride treated BP	Postoperative 1 g of cephaporin sodium and 500 mg of amoxicillin twice/day for 7 days	29.6 (25–34)§	100% successful No complication	1
Leungwattanakij et al. [27], 2000	USA	20 rats	Male	– (0.3–0.325)	Penile reconstruction	1 = Control 2 = Excision plus Tutoplast HCP graft	Tunica albuginea substitution after wedge excision	Tutoplast HCP graft	5 days postoperative antibiotics	16	100% successful	1
Portis et al. [23], 2000	USA	6 pigs	Female	NR	Laparoscopic bladder reconstruction	1 = Control 2 = Porcine bowel ATM 3 = BP 4 = HPM 5 = Porcine SIS	Bladder augmentation after partial cystectomy	Periguard BP	Ceftiofur100 mg for 10 days postoperative and Antibiotics in animals with infection at follow-up	3	100% rejection	1
Leungwattanakij et al. [55], 2003	USA	30 rats	Male	– (0.3–0.325)	Penile reconstruction	1 = Sham 2 = HCP 3 = Vein graft	Tunica albuginea substitution after wedge excision	Tutoplast HCP	Antibiotics for 5 days after surgery	4	100% successful with moderate fibrosis	2
Leungwattanakij et al. [54], 2003	USA	20 rats	Male	– (0.3–0.325)	Penile reconstruction	1 = Sham 2 = HCP 3 = Dermis graft 4 = Vein graft 5 = Gore-Tex graft	Tunica albuginea substitution after wedge excision	Tutoplast HCP graft	Antibiotics for 5 days after surgery	6	100% successful minimal fibrosis	2
Lara et al. [53], 2004	Brazil	30 dogs	Male	NR	Urethral reconstruction	NA	Urethral defect	BP graft treated with buffered glutaraldehyde and preserved in formaldehyde	400,000 IU of procaine penicillin, 600,000 IU of benzathine penicillin G and 40 mg of gentamicin	24	20% successful	0

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Table 2. (continued)

Author	Country	Number of subjects	Gender	Mean of weight, kg*	Surgery type	Study groups	Setting/disease	Pericardium type	Perioperative medical therapy	Follow-up duration, week†	Overall outcomes	NOS score
Ayyildiz et al. [51], 2006	Turkey	5 rabbits	Male	2.850 (2.5–3.15)	Penile reconstruction	1= Primary repair 2= Free graft 3 = Allograft fascia lata 4 = Alloderm 5 = BP graft	Urethrocutaneous fistulas	BP graft	A single dose of 20 mg/kg of ceftriaxone	3	100% successful	1
Mimura et al. [56], 2010	Japan	5 rats	Female	0.337	Bladder reconstruction	1 = Non-augmented 2 = Procine SIS 3 = BP-derived biomaterial	Bladder augmentation	Acellular BP-derived material	NA	8	100% successful	2
Kajbafzadeh et al. [25], 2011	Iran	12 rabbits	Male	3	Bladder reconstruction	1 = Control 2 = TEP‡ 3 = Autologous muscle fragment-seeded TEP 4 = Autologous SMC-seeded TEP	Bladder augmentation	TEP	Penicillin plus streptomycin plus amphotericin	8	100% successful	1
Sandomirsky et al. [24], 2016	Ukraine	18 rabbits	Female	– (3.1–4)	Bladder reconstruction	NR	Bladder wall defect	Cryoirradiation modified PP	NR	12	100% successful	0

* Weight is presented as mean (range).
† Follow-up duration is presented as mean.
‡ TEP is made of a pericardial tissue from a young pure-bred female 'Lovenaar' sheep.
§ This follow-up duration is presented as month.
NOS, Newcastle – Ottawa quality assessment scale; BP, bovine pericardium; HCP, human cadaveric pericardium; SIS, small intestinal submucosa; TEP, tissue-engineered pericardium; SMC, smooth muscle cell; PP, porcine pericardium; ATM, acellular tissue matrix; HPM, human placental membranes; SIS, small intestinal submucosa.

Study or subgroup	Pericardial-based graft Events	Total	Comparator Events	Total	Weight	OR M-H, fixed, 95% CI
Chun et al., 2001	1	9	4	15	16.6%	0.34 [0.03, 3.69]
Taylor et al., 2008	20	81	11	61	58.8%	1.49 [0.65, 3.40]
Usta et al., 2003–1	5	19	4	31	13.9%	2.41 [0.56, 10.43]
Usta et al., 2003–2	2	11	4	31	10.7%	1.50 [0.23, 9.61]
Total, 95% CI		120		138	100.0%	1.43 [0.76, 2.69]
Total events	28		23			

Heterogeneity: Chi^2 = 1.89, df = 3 (p = 0.60); I^2 = 0%
Test for overall effect: Z = 1.11 (p = 0.27)

a

Study or subgroup	Pericardial-based graft Events	Total	Comparator Events	Total	Weight	OR M-H, fixed, 95% CI	Year
Chun et al., 2001	0	9	2	15	10.7%	0.28 [0.01, 6.62]	2001
Usta et al., 2003–1	3	19	0	31	1.9%	13.36 [0.65, 274.51]	2003
Taylor et al., 2008	25	81	19	61	87.5%	0.99 [0.48, 2.02]	2008
Total, 95% CI		109		107	100.0%	1.14 [0.60, 2.18]	
Total events	28		21				

Heterogeneity: Chi^2 = 3.45, df = 2 (p = 0.18); I^2 = 42%
Test for overall effect: Z = 0.40 (p = 0.69)

b

Study or subgroup	Pericardial-based graft Events	Total	Comparator Events	Total	Weight	Risk ratio M-H, fixed, 95% CI	Year
Usta et al., 2003–2	3	19	1	31	8.8%	4.89 [0.55, 43.73]	2003
Usta et al., 2003–1	1	11	1	31	6.1%	2.82 [0.19, 41.31]	2003
Chung et al., 2011–2	4	23	5	17	66.7%	0.59 [0.19, 1.88]	2011
Chung et al., 2011–1	4	23	1	6	18.4%	1.04 [0.14, 7.70]	2011
Total, 95% CI		76		85	100.0%	1.09 [0.54, 2.63]	
Total events	12		8				

Heterogeneity: Chi^2 = 3.42, df = 3 (p = 0.33); I^2 = 12%
Test for overall effect: Z = 0.43 (p = 0.67)

c

Study or subgroup	Pericardial-based graft Events	Total	Comparator Events	Total	Weight	Risk ratio M-H, fixed, 95% CI	Year
Chun et al., 2001	4	9	4	15	44.7%	1.67 [0.55, 5.07]	2001
Usta et al., 2003–2	1	11	2	31	15.6%	1.41 [0.14, 14.05]	2003
Usta et al., 2003–1	3	19	2	31	22.7%	2.45 [0.45, 13.34]	2003
Taylor et al., 2008	4	81	1	61	17%	3.01 [0.35, 26.28]	2008
Total, 95% CI		120		138	100%	2.03 [0.90, 4.61]	
Total events	12		9				

Heterogeneity: Chi^2 = 0.39, df = 3 (p = 0.94); I^2 = 0%
Test for overall effect: Z = 1.70 (p = 0.09)

d

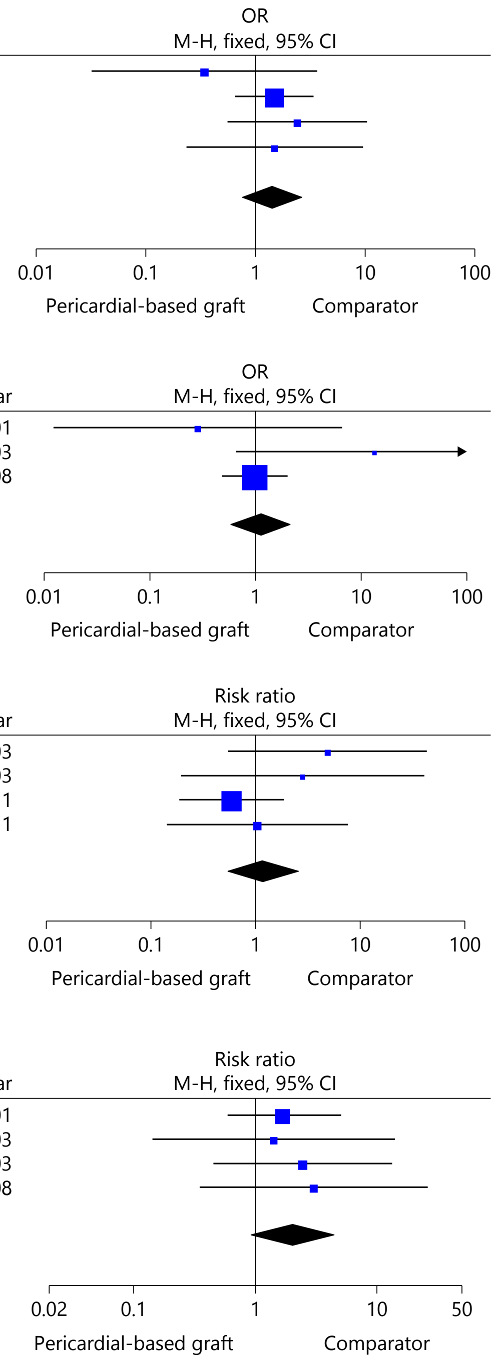

Fig. 2. Effects of the pericardial graft versus the comparators on (**a**) dissatisfaction rate, (**b**) glans hypoesthesia, (**c**) penile shortening, and (**d**) penile curvature abnormalities in patients undergoing penile reconstructive surgeries. Penile curvature was defined as a remaining curvature of greater than 30° whether or not it interfered with the patient's coitus or a recurrent curvature.

DOI: 10.1159/000495513

Animal Studies

Among the animal studies, 4 reports used either HCP or BP during successful penile reconstructions [27, 51, 54, 55]. Two studies reported minimal to moderate fibrosis in BP grafts at the last follow-up. Moreover, there was no significant difference between the HCP grafts and the comparators (i.e., sham/control, vein grafts, dermal grafts, or polytetrafluoroethylene) in terms of the stimulated intracorporeal pressure at the last follow-up [27, 54]. Further details of the perioperative outcomes are presented in online supplementary Table 3.

Based on pooled results, the amount of the stimulated intracorporeal pressure 5 V at the last follow-up in the animals undergoing penile reconstruction with HCP grafts was comparable with the comparators (RR 0.98, 95% CI –1.97 to 3.93, $p = 0.51$; $I^2 = 78\%$). The level of the stimulated intracorporeal pressure 7.5 V at the last follow-up was also comparable between HCP and the comparators (RR –3.97, 95% CI –10.08 to 2.14, $p = 0.20$; $I^2 = 94\%$; online suppl. Fig. 2). There was significant publication bias (online suppl. Fig. 3). After the exclusion of outlier studies, the pooled result of the stimulated intracorporeal pressure 5 V significantly favored pericardial grafts without heterogeneity (RR 2.61, 95% CI 1.26–3.97, $p = 0.0002$; $I^2 = 0\%$). In contrast, the pooled result of the stimulated intracorporeal pressure 7.5 V remained similar and with significant heterogeneity (RR 0.29, $p = 0.87$; $I^2 = 82\%$). After the exclusion of outlier studies, publication bias disappeared in both analyses based on funnel plots too.

Seven studies used pericardial grafts for the reconstruction of bladder wall defects [23–25, 52, 56–58]. All procedures were successful at the last follow-up; however, the reconstruction procedure failed in 6 mini pigs, in which BP grafts were implanted laparoscopically to augment the bladder wall defects [23]. Moreover, 1 of 5 (20%) dogs undergoing bladder reconstruction showed signs of urine leakage at the first week of the postoperative period, and there was a defect in the anastomosis part [57]. Moreover, treated BP grafts were used for the reconstruction of urethral defects in 30 dogs, during which 80% of the animals presented with urethrocutaneous fistulae without stenosis, and one dog with a successful procedure died of respiratory infections 4 months later [53].

Discussion

To the best of our knowledge, the present review is the first of its kind to provide a comprehensive overview of the utility of the pericardial tissue in reconstructive urologic surgeries. Our findings revealed that the implementation of pericardial-based grafts is feasible in human and animal models. Additionally, it is associated with good results and – in some ways – its outcome is similar to that of other grafts used in penile reconstruction. However, the majority of the studies concerning the pericardial tissue in the bladder, kidney, or urethra are case reports or small series. The results are promising, but it seems that further research is necessary, particularly in complicated urethral surgeries with long defects and bladder reconstruction in humans. In addition, based on animal studies, the use of the pericardial tissue is feasible in the majority of urologic surgeries, except for bladder wall reconstruction.

Pericardial Tissue Features and Feasibility

For all the great advances in the use of synthetic biomaterials for surgeries, no material has been proved to be comparable to biological tissues [59]. The pericardial tissue, as a widely used biomaterial, has excellent biomechanical features, which make it a feasible graft in many kinds of surgeries. The pericardium tissue, either human or animal type, is composed of collagen, elastin fibers, and extracellular matrix [60]. Not only is BP inexpensive, but also it possesses such features as elasticity, lack of transmission of diseases, low rate of retraction, and good tension tolerance [10]. After treatment in glutaraldehyde, BP turns into a strong, easy-to-handle, durable, and low antigenic graft. Nevertheless, it may have a high rejection rate and adhesion to surrounding tissues, be more allergic, and be associated with calculi formation in patients undergoing urologic or vascular surgeries [8, 61]. In contrast, BP has been demonstrated to be associated with no evidence of calcification, infection, thromboembolic events, or failure in pediatrics undergoing cardiac surgeries [62, 63]. Additionally, it is deemed an appropriate graft in infected tissues [62].

Another type of the pericardium graft is the HCP, which has been implemented in more than 750,000 operations since the 1970s without any adverse events or infection transmission [64, 65]. The main disadvantages, however, are its relatively high costs and possible poor availability [9, 66]. Tutoplast® is a patented form of the HCP graft. The Tutoplast® process eradicates cellular material and microorganisms in a 4-step process, including a solvent dehydration step and a subsequent gamma irradiation [66]. This acellular collagenous graft provides a scaffold for the regeneration of the native tissue [41].

Based on our findings, there is no study to compare the efficacy of HCP with that of BP in urologic surgeries. Be that as it may, we found that the outcomes of operations using HCP were comparable to other substitutes/controls in the setting of penile reconstruction, although there was a trend among the patients with HCP grafts toward having a more penile curvature (defined as a curvature >30° whether or not it interfered with the patients' coitus or recurrent curvature). Despite these findings, we cannot present a more robust conclusion regarding the efficacy of pericardial tissues in this setting. Further studies are required to address detailed outcomes of interest.

The main factors influencing the biomechanical features of the pericardial tissue arise from chemical agents and mechanical tools used for preparing and treating the tissue before application in recipients. The glutaraldehyde-fixed pericardium is the choice for bioprosthetic valve preparation, but this method may be accompanied by calcification caused by the lack of complete biocompatibility in human bodies in some preparation methods [67, 68]. Santoro et al. [69] found that the fixative-free decellularization of BP seeded with the interstitial cells of the aortic valve could be a more immunocompatible tissue and be used to develop tissue-engineered heart valves with seeded cells. Kajbafzadeh et al. [25] demonstrated that tissue-engineered sheep pericardium seeded with autologous bladder smooth muscle cells might improve the efficacy of the pericardium in the regeneration of the bladder wall. Further studies with respect to the methods of pericardium fixation and the use of new methods of seeding with autologous cells may provide more promising results in urologic surgeries.

Penile Surgeries

Biological materials such as oral mucosa, dermis, vein, fascia temporalis, tunica vaginalis, and part of the albuginea of the corpora cavernosa have been exploited in penile reconstruction [18]; however, they cannot be considered ideal substitutes, mainly due to their low tensile strength [9, 66, 70]. The pericardium tissue has been extensively used in penile straightening surgeries because it has multidirectional expansion of up to 30% and excellent tensile strength, making it an ideal graft for the tunica and appropriate thickness for intraoperative handling [66]. The use of HCP for penile reconstruction was first announced by Hellstrom and Reddy [66]. They reported a higher rate of erectile dysfunction in patients with larger grafts [9]. Based on our review, the success rate of HCP grafts has been relatively low, approximately 75% compared with a success rate of about 98% in BP grafts. Flores et al. [35] demonstrated that the use of HCP might not be a good option for old patients with higher penile curvature and venous leak at baseline. In contrast, Taylor and Levine [46] found that the long-term outcomes of tunica albuginea plication and pericardial graft plus plaque excision were similar at the expense of having an increased risk of erectile dysfunction requiring adjuvant therapies. They concluded that both techniques could be used in men with significant Peyronie's disease. Although our meta-analysis showed no significant difference between HCP and the comparators in the human and animal models, there was more penile curvature among the patients receiving HCP grafts for penile reconstruction. The absence of well-designed and large-scaled studies precluded us from reaching a definite conclusion with regard to the feasibility of pericardium-based grafts in penile reconstruction.

Urethral Surgeries

The repair of large urethral strictures and defects needs substitutes when bladder flaps and transureteroureterostomy prove inadequate. The frequently used grafts for urethroplasty include small intestine [2] and autografts derived from the buccal mucosa and foreskin [71, 72]. Other grafts for urethroplasty include human tissues (i.e., lingual mucosa, bladder mucosa, and appendix) or biomaterials (e.g., acellular collagen matrix and small intestine submucosa) [73–75]. There are scarce data regarding the use of the pericardial tissue in urethroplasty. Lara et al [53] used treated BP for urethroplasty in dogs and showed a high rate of failure (80%) caused by urethrocutaneous fistulae without stenosis. Six dogs with successful operations had complete epithelialization of the urethra on microscopic evaluation. If the development of fistulae is avoidable, we may postulate that BP grafts may be another option for urethroplasty. Moreover, in a pilot study by Pelosi et al. [42] processed BP, as a YAMA UroPatch sling, was utilized in 22 patients to manage female urinary incontinence. All procedures were successful and 95.4% of the patients were reported as cured. The main advantages of BP grafts include its softness, pliability, and lack of shrinkage, conferring easy implementation and handling [42]. In addition, in a patient undergoing the repair of urethral diverticulum, a BP graft was successfully applied [37]. Although autologous fascial sling has grade A recommendation, morbidity caused by harvest of tissues prompted use of biological grafts [76]. On the other hand, some other materials for the same purpose showed inconsistent results. Siracusano et al. [77] found that porcine small intestinal submucosa implantation in female patients with stress urinary incontinence cannot confer a durable graft. In contrast, Rutner et al. [78] found it durable and strong for similar intervention. It seems that the pericardial tissue may be another option in urethroplasty, but larger studies with longer follow-up in patients with different indications for reconstructive surgery are required to clarify its feasibility.

Bladder Surgeries

The augmentation of the bladder wall is done using different materials. Of these, seeded or non-seeded intestine is regarded as the gold standard, although it has been associated with such complications as metabolic acidosis, recurrent infections, calculi, and the risk of cancer [79, 80]. The natural function and structure of the bladder has been a great obstacle to finding an appropriate substitute. The pericardium has been utilized in animal models of bladder reconstruction, and approximately 83% of the operations were successful [23–25, 52, 56–58]. Only 2 patients underwent bladder reconstruction using treated BP, during which enterovesical fistulae and defects of the bladder wall in a post-irradiated pelvis were repaired [8, 11]. Although the success rate has been relatively good, short follow-up is the main limitation in the evaluation of these procedures. It has been postulated that the regeneration of a new tissue on a pericardial graft may take weeks to years, and some factors such as graft size, location, and postoperative inflammation may influence the outcome [66]. Moreover, tissue-engineered materials, in which the pericardial tissue is seeded with bladder allogeneic cells, may be associated with promising results in humans – similar to the findings of this technique in animal models [25]. Moreover, given previous studies, we think that muscle flaps for bladder reconstruction and seeding grafts with bladder muscle cells may constitute other modalities [25]; however, there is a lack of data regarding these options in human surgeries. The use of the human pericardium in this setting merits further trials in the search for the best option.

Kidney Surgeries

Partial nephrectomy is the technique of choice for the resection of small tumors, but it is associated with urine leak, bleeding, and fistula formation, which are assumed to be caused by the incomplete closure of the renal capsule [81]. In a single case of kidney reconstruction, BP was successfully used to close the renal capsule [48]. In a previous report, polytetrafluoroethylene was associated with good outcomes after partial nephrectomy, but it was a single case. It seems advisable that further studies be conducted to explore the applicability and efficacy of the pericardial tissue for kidney reconstructive surgeries.

Limitations

Some limitations should be taken into consideration in the interpretation of our findings. First, there were some case reports regarding the use of the pericardium that their results cannot be generalizable. Indeed, more research is required to explore pericardium utility in urologic surgeries, particularly in urethroplasty, bladder reconstruction, and kidney reconstruction. Second, the absence of more studies comparing different types of grafts with the pericardium substitute precludes us from extensively analyzing the outcomes of interest. Third, the collagenous matrix forms a framework for the regeneration of original tissues. The process begins 1–2 days after surgery and possibly takes weeks to years, whereas the majority of studies had a follow-up duration of less than 1 year [66].

In this review, we present an overview of pericardium utility in reconstructive urologic surgeries in human and animal models. Experimental studies in healthy or simulated diseased animals appear to demonstrate the feasibility of the pericardial tissue, regardless of its type and preparation method. Moreover, similar results were also observed in human studies, although they had some limitations with respect to their outcome measurements and short-term follow-ups. Given the shortcomings, the use of pericardial grafts in reconstructive urologic surgeries needs further attention – not least in human studies – to explore its pros and cons in comparison with other grafts. In addition, there are many situations and cases, in which the tissues routinely drawn upon for urethral replacement may prove inadequate and the pericardium – on the strength of its good length and tensility – might be deemed a suitable substitute. Moreover, the pericardial tissue could be extended to more reconstructive surgeries provided that further large-scaled studies are undertaken to examine the histological and mechanical properties of pericardial grafts.

Disclosure Statement

None of the contributing authors have any conflict of interest, including specific financial interests or relationships and affiliations relevant to the subject matter or materials discussed in the manuscript.

Authors Contribution

J.H., S.H., and Y.R. were in charge of project development; data collection and data analysis were done by Y.R. and M.A.H.; manuscript writing was done by Y.R.; manuscript editing was done by J.H., S.H., M.A.H., and Y.R.

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