

SYSTEMATIC REVIEW

Editor's Choice — Cryopreserved Allografts for Arterial Reconstruction after Aorto-Iliac Infection: A Systematic Review and Meta-Analysis

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WHAT THIS STUDY ADDS

This meta-analysis on the role of cryopreserved allografts for arterial reconstruction after aorto-iliac infection is the first to review all available data from 31 studies, including 1,377 patients. Pooled proportions for 30 outcomes were estimated, and it was found that the use of cryopreserved allograft seems to be a safe and durable option. This reinforces their potential as alternatives to extra-anatomic bypass or use of autologous veins for treatment of aorto-iliac infection.

Objective: Native and aortic graft infections are rare, but they represent one of the most life threatening complications of vascular surgery. Several materials and surgical approaches have been developed so far. Among them, cryopreserved allografts have been proposed as a treatment option. A systematic review and meta-analysis was conducted to investigate the role of cryopreserved allografts for arterial reconstruction after aorto-iliac infection.

Methods: The current meta-analysis was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Patient baseline characteristics were investigated, along with 30 outcomes after use of cryopreserved arterial allografts for reconstruction after aorto-iliac infection. Pooled proportions with 95% CIs of outcome rates were calculated.

Results: A total of 31 studies, including 1,377 patients, finally participated in the meta-analysis. Among the early outcomes, 30 day mortality was 14.91% (95% CI 11.78–18.31). Peri-anastomotic rupture/allograft disruption rate was 5.90% (95% CI 2.77–9.88), while pooled aneurysmal degeneration/allograft dilatation was 4.99% (95% CI 1.60–9.68). A pooled rate of 3.11% (95% CI 1.60–4.98) was estimated for pseudoaneurysm formation after the use of cryopreserved arterial allografts, while the allograft thrombotic/stenotic complication rate and peri-anastomotic infection were 12.19% (95% CI 7.90–17.15) and 3.32% (95% CI 1.90–5.03), respectively. Mortality during follow up was 19.24% (95% CI 11.97–27.58), while allograft related mortality during follow up was 3.58% (95% CI 1.56–6.15). A pooled allograft related re-operation rate was estimated at 24.87% (95% CI 17.89–32.51).

Conclusions: The use of cryopreserved allograft seems to be a safe and durable option with acceptable outcomes for treatment of aorto-iliac infection.

Keywords: Allografts, Cryopreservation, Infection, Meta-analysis, Reconstructive surgical procedures, Review

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INTRODUCTION

Infection of native abdominal aorta and prosthetic grafts still remains one of the greatest challenges in vascular surgery, with a high morbidity and mortality even after

successful intervention. The basic principle behind the treatment of aortic graft infection is an extensive debridement, with prosthetic aortic graft excision and concomitant extra-anatomic or anatomic revascularisation, along with repair of the bowel lesion in many cases. However, a disadvantage of the extra-anatomic method is the risk of aortic stump blowout, which is usually fatal.^{1–3} This has led to growing interest in *in situ* replacement using other materials, including antibiotic or silver coated prosthesis, autogenous veins, and pericardial tissue. Among these alternatives, *in situ* revascularisation with cryopreserved

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allograft has been proposed with favourable outcomes, incorporating the advantage of a thick walled autogenous conduit which seems to be more resistant to re-infection and rupture.⁴ However, results using this technique are diverse and conflicting among the studies, and so far no systematic review has been performed to pool all available data together and there is no definite indication in the existing guidelines.

The aim of this study was to conduct a systematic review and meta-analysis of the published literature assessing the outcomes of cryopreserved allografts for arterial reconstruction after aorto-iliac infection.

MATERIALS AND METHODS

Data collection, search methodology, inclusion and exclusion criteria

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used to perform the current meta-analysis. Medline, Scopus, EMBASE, Google Scholar, Ovid, the Cochrane Library and 15 “related items” in PubMed library were systematically searched for articles of interest, and the reference lists of the eligible articles were further searched for additional potentially eligible articles.

The Medical Subject Headings (MESH) terms used for the search purpose were: “graft”[All Fields], “allograft”[All Fields], “homograft”[All Fields], “xenograft”[All Fields], “autograft”[All Fields], and “cryopreserved”[All Fields]. The search covered all scientific papers, without gender or language restriction from January 1960 to September 2018. Two authors (CNA, NAP) independently performed the search and selection of studies, extracted and analysed data, and the final decision was reached by discussion and consensus. Studies were investigated focusing on the use of cryopreserved arterial allografts for arterial reconstruction after abdominal aortic native or secondary graft infection. Studies reporting any type of graft other than cryopreserved arterial allografts were excluded.

Baseline characteristics

Data extracted from eligible studies included the first author’s name, study year, country in which the study was conducted, total number of patients, number of males, mean age of study participants, prior medical history, indications for treatment, type of initial surgical procedure, indications for treatment, micro-organisms detected pre-/intra-operatively, type of surgical reconstruction performed, mean interval from the initial aortic graft insertion to diagnosis of infection or allograft placement (months), median time between diagnosis of infection and surgical reconstruction (days), median hospital stay (days), primary patency rate, follow up (months), and number of patients under follow up.

Outcomes of interest

The numbers of patients with 30 outcomes of interest were also extracted. The outcomes were categorised as:

Early mortality. ($n = 2$): 1) 30 day mortality and 2) intra-operative mortality

Graft related complication. ($n = 5$): 1) peri-anastomotic rupture/allograft disruption, 2) aneurysmal degeneration/allograft dilatation, 3) pseudoaneurysm, 4) allograft thrombotic/stenotic complications, 5) peri-anastomotic infection

Patient related complication. ($n = 19$): 1) myocardial ischaemic complications, 2) cardiac rhythm complications, 3) respiratory complications, 4) acute renal failure, 5) urinary tract complications, 6) neurological complications, 7) venous thrombosis, 8) compartment syndrome, 9) sepsis/multi-organ failure, 10) enteric perforation, 11) prolonged ileus, 12) cholopancreatic complications, 13) intra-abdominal bleeding, 14) wound complications, 15) systemic infections, 16) amputation, 17) haemorrhagic complications, 18) aorto-enteric fistulas, 19) colonic arterial blood supply complications

Late mortality. ($n = 2$): 1) mortality during follow up, 2) graft related mortality during follow up

Reoperations. ($n = 2$): 1) re-operations (any), 2) graft related reoperations

Statistical analyses

Data synthesis and treatment effects, heterogeneity, and publication bias. The outcome rates in patients treated with cryopreserved arterial allografts for arterial reconstruction after native abdominal aortic or secondary graft infection were estimated for each study and reported as the proportion of patients with the corresponding outcome among all patients treated with cryopreserved arterial allografts. Values of the concomitant outcomes were subsequently appropriately calculated, expressed as proportions and 95% CIs and thereafter transformed into quantities according to the Freeman-Tukey variant of the arcsine square root transformed proportion. The pooled effect estimates were calculated as the back transformation of the weighted mean of the transformed proportions, using DerSimonian-Laird weights of random effects model and expressed as % proportions.⁵ A formal statistical test for heterogeneity using the I^2 test was performed. Publication bias was assessed using the Egger’s test for small study effects, as well as visual inspection of funnel plots. The STATA statistical software v14 (Stata Corp LP, USA) was used for the analyses.

Quality assessment of eligible studies

All eligible studies were evaluated using a novel 20 item quality appraisal checklist for case series studies. This tool included two components: the first indicated the extent to which a case series presented traditional features of a statistical hypothesis testing paradigm, whereas the second evaluated detailed descriptions of the subjects’ characteristics particularly in relation to potential source of confounding.⁶

RESULTS

Study characteristics

The literature search identified 789 potentially eligible studies. After review of the titles and abstracts and application of inclusion and exclusion criteria, 742 articles were excluded. Two more articles were excluded for reporting reasons.^{7,8} Four articles included overlapping populations with the eligible studies^{9–12} and four articles reported outcomes not for cryopreserved grafts^{13–16} and were excluded from the analysis. Three articles were case reports^{17–19} and three were reviews,^{20–22} and they were also excluded. This left 31 articles^{1–4,23–49} for the meta-analysis (Fig. S1), corresponding to a total of 1,377 patients who received arterial allografts for aortic infection.

Baseline study characteristics of the 31 eligible studies included in the systematic review are presented in Table S1. The study period of all included studies ranged from 1966³⁸ to 2017.^{1,31,36} Interestingly, the first reported study included a high volume of 116 patients treated with cryopreserved allografts.³⁸ Males comprised 74.2%

of the entire patient cohort with a mean age >60 years. Eighteen of the 31 studies (58%) were conducted either in France or in the USA. Cryopreserved arterial allografts were used for the treatment of aorto-iliac occlusive or aneurysmal disease in the two studies published before 1970,^{38,45} whereas prosthetic aortic graft infection with or without aorto-enteric fistula was the main indication for studies after 1996. Surprisingly, no study was published between 1970 and 1996. Aorto-bi-iliac or aortobi-femoral aortic reconstruction was the surgical reconstruction performed in the vast majority of cases. The mean interval from the initial aortic graft implantation to the diagnosis of the prosthetic graft infection and consequent allograft placement ranged from 4 to 92 months. Among the most prevalent comorbidities were hypertension, smoking, and coronary artery disease. *Staphylococcus* species were the most common microorganisms detected pre- or intra-operatively, whereas polymicrobial infection was also detected in high frequency. Median hospital stay was over two weeks in almost all studies, while median follow up ranged from

Table 1. Results of the meta-analysis

Outcome category	Outcome	No. of studies n	Effect estimate Pooled outcome rate % (95% CI)	Heterogeneity I^2 (p value)	Publication bias t (p value)
Early mortality	30 day mortality	27	14.91 (11.78–18.31)	54.5 (< .01)	1.68 (.11)
	Intra-operative mortality	13	0.30 (0.00–1.34)	0.0 (.68)	0.52 (.62)
Graft related	Peri-anastomotic rupture/allograft disruption	15	5.90 (2.77–9.88)	71.2 (< .01)	1.04 (.32)
	Aneurysmal degeneration/allograft dilatation	15	4.99 (1.60–9.68)	76.8 (< .01)	0.09 (.93)
	Pseudoaneurysm	10	3.11 (1.60–4.98)	8.6 (.36)	–0.56 (.59)
	Allograft thrombotic/stenotic complications	24	12.19 (7.90–17.15)	78.6 (< .01)	0.13 (.90)
Patient related	Peri-anastomotic infection	14	3.32 (1.90–5.03)	31.9 (.13)	0.43 (.67)
	Myocardial ischaemic complications	8	5.58 (3.08–8.62)	0.0 (.80)	1.69 (.14)
	Cardiac rhythm complications	2	2.31 (0.00–7.12)	–	–
	Respiratory complications	9	12.86 (9.42–16.68)	4.8 (.10)	0.80 (.45)
	Acute renal failure	10	6.07 (3.76–8.78)	0.0 (.58)	2.76 (.03)
	Urinary tract complications	3	1.35 (0.00–5.57)	0.0 (.66)	0.08 (.95)
	Neurological complications	7	4.25 (1.71–7.58)	0.0 (.96)	1.00 (.36)
	Venous thrombosis	5	9.24 (5.03–14.37)	0.0 (.63)	–1.23 (.31)
	Compartment syndrome	4	0.60 (0.00–2.04)	5.3 (.37)	6.70 (.02)
	Sepsis/multi-organ failure	9	6.99 (4.81–9.49)	0.0 (.56)	–0.30 (.77)
	Enteric perforation	5	0.56 (0.00–2.15)	33.6 (.20)	13.98 (.001)
	Prolonged ileus	5	4.00 (1.31–7.69)	0.0 (.98)	1.58 (.21)
	Cholopancreatic complications	2	3.92 (0.00–11.97)	–	–
	Intra-abdominal bleeding	4	3.43 (1.11–6.67)	28.9 (.24)	2.16 (.16)
	Wound complications	9	8.76 (3.59–15.54)	68.2 (< .01)	–0.41 (.70)
	Infectious complications	5	2.68 (0.60–5.71)	11.02 (.34)	–0.55 (.62)
	Amputation	13	3.78 (1.93–6.04)	13.4 (.31)	0.54 (.60)
Late mortality	Haemorrhagic complications	5	4.29 (0.76–9.75)	54.8 (.06)	0.89 (.44)
	Aorto-enteric fistula	7	3.46 (1.19–6.53)	0.0 (.79)	1.51 (.19)
	Colonic arterial blood supply complications	5	5.03 (1.20–10.67)	54.1 (.07)	0.66 (.56)
	Mortality during follow up	27	19.24 (11.97–27.58)	88.8 (< .01)	1.34 (.19)
	Graft related mortality during follow up	22	3.58 (1.56–6.15)	52.64 (< .01)	1.98 (.06)
Reoperations	Any reoperations	22	24.87 (17.89–32.51)	82.7 (< .01)	1.01 (.32)
	Graft related reoperations	17	23.52 (15.94–31.97)	81.5 (< .01)	1.49 (.16)

CI = confidence interval; I^2 = percentage of variation.

6.2 to 53 months. Freedom from re-operation rate was rather high; in all but seven studies, it was >75%, while in 10 studies, it was >85%. Cryopreserved allografts were patent in >56% of cases among the studies that reported patency rates, while in the majority of studies reporting late outcomes, patency rates ranged from 81% at three years to 97% at five years follow up. Quality assessment of the eligible studies showed that, although they were retrospective in nature and case series, they were mostly of sufficient study design and execution (Table S2).

Meta-analysis

Pooled outcome rates with 95% CIs and estimations of heterogeneity and publication bias are presented in Table 1. A total of 27 studies reported data on 30 day mortality, which was estimated at 14.91% (95% CI 11.78–18.31; Fig. 1). The peri-anastomotic rupture/allograft disruption

rate was 5.90% (95% CI 2.77–9.88; Fig. 2), while pooled aneurysmal degeneration/allograft dilatation was 4.99% (95% CI 1.60–9.68; Fig. 3). A pooled rate of 3.11% (95% CI 1.60–4.98) was estimated for pseudoaneurysm formation after use of cryopreserved arterial allografts, while allograft thrombotic/stenotic complications rate and peri-anastomotic infection was 12.19% (95% CI 7.90–17.15) and 3.32% (95% CI 1.90–5.03), respectively. Mortality during follow up was 19.24% (95% CI 11.97–27.58), while allograft related mortality during follow up was 3.58% (95% CI 1.56–6.15; Fig. 4). Furthermore, a pooled re-operation rate was estimated at 24.87% (95% CI 17.89–32.51). All outcomes are shown in Table 1.

DISCUSSION

The present meta-analysis has estimated a pooled early mortality of <15%, with almost zero intra-operative

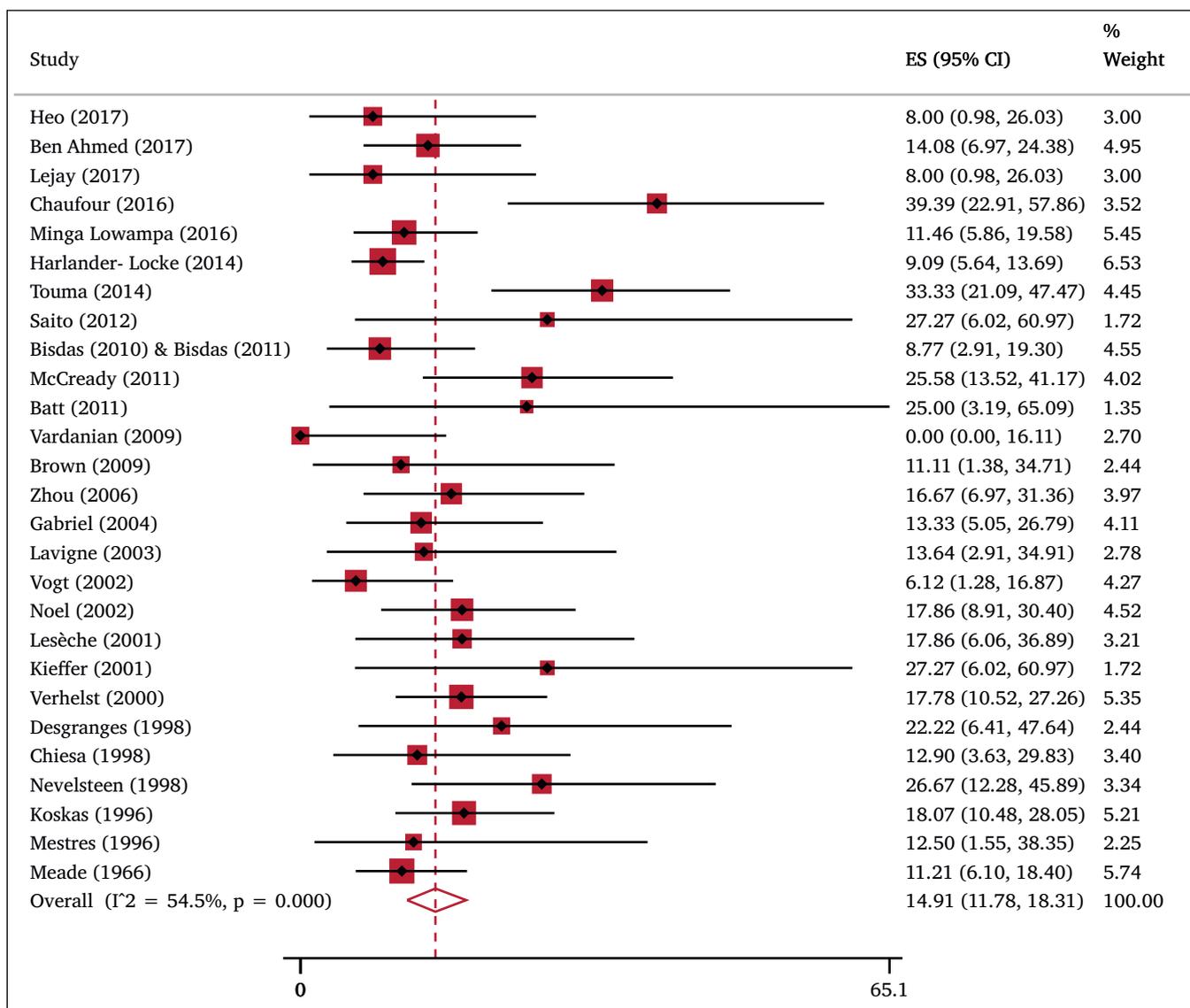
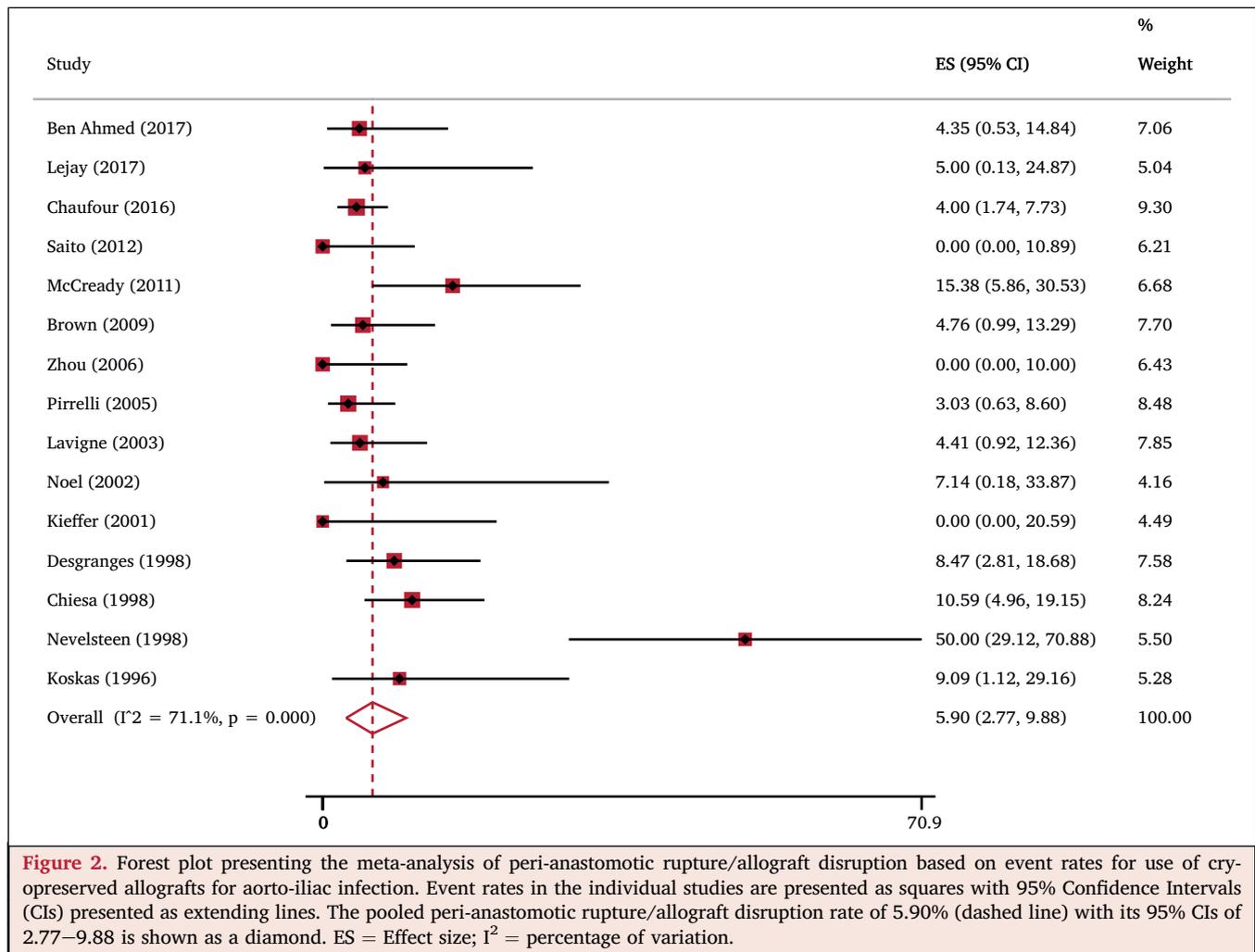


Figure 1. Forest plot presenting the meta-analysis of 30 day mortality based on event rates for use of cryopreserved allografts for aorto-iliac infection. Event rates in the individual studies are presented as squares with 95% Confidence Intervals (CIs) presented as extending lines. The pooled 30 day mortality rate of 14.91% (dashed line) with its 95% CIs of 11.78–18.31) is shown as a diamond. ES = Effect size; I² = percentage of variation.

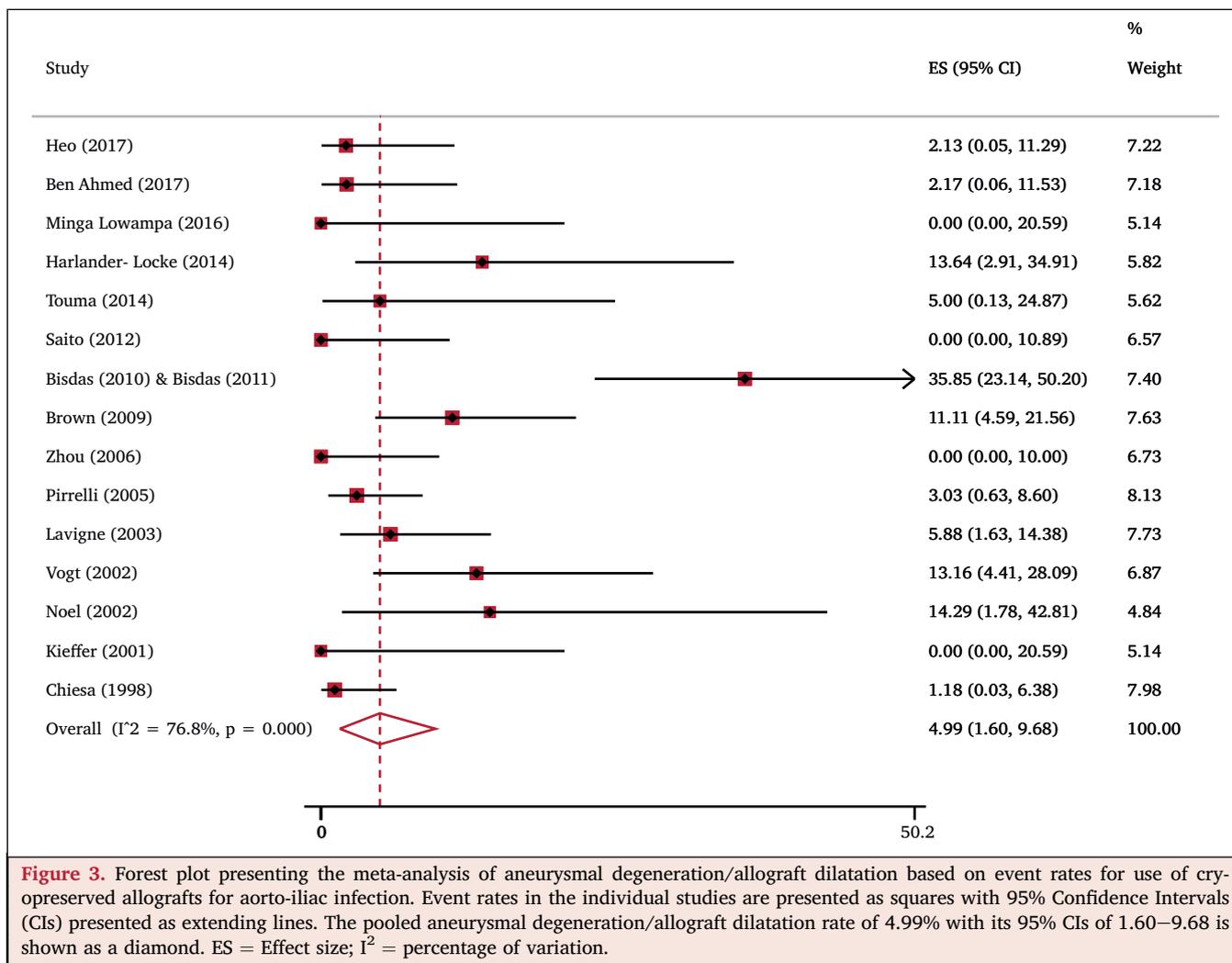


mortality. Late mortality was 20%; however, <4% was attributed to the complications of the technique, again highlighting its safety. Complications after surgery concerning the use of the cryopreserved allograft, such as anastomotic rupture, allograft degeneration, and pseudoaneurysm formation were between 3% and 6%. Importantly, 14 studies reported on re-infection rates and the pooled rate was estimated at a low of 3%. Complications after surgery were mainly respiratory. These figures taken together, point to the durability of the technique, adding a good alternative for treating aorto-iliac native and synthetic graft infection.

The risk of native aortic or prosthetic graft infection, although rare at 0.2–5% of all open aortic repairs,³⁰ has remained stable over the past two decades, indicating a continuing life threatening condition and at the same time posing the greatest challenge in vascular surgery. Ideally, the treatment involves removal of the infected graft material, along with all surrounding necrotic tissues and inline arterial reconstruction, which can be performed with extra-anatomic bypass. However, because of the high potential risk of aortic stump blowout with this technique, *in situ* reconstruction followed by omental wrapping has been used as an alternative. Many different types of synthetic graft have been tested for that reason, mainly irrigated with

rifampicin or triclosan. Moreover, new prostheses, such as silver coated, covalent bonded silver coated prostheses, or the novel glutaraldehyde fixed bovine collagen with an integrated polyester graft have shown good patency rates. However, the re-infection rates with these grafts may vary from 4% to 17%, which led to another treatment option, arterial reconstruction using femoral veins (neo-aorto-iliac system), with good results. However, even this operation is not ideal; it is lengthy, with significant venous morbidity, including post-operative fasciotomy and higher late rupture rate and secondary interventions.^{1,36}

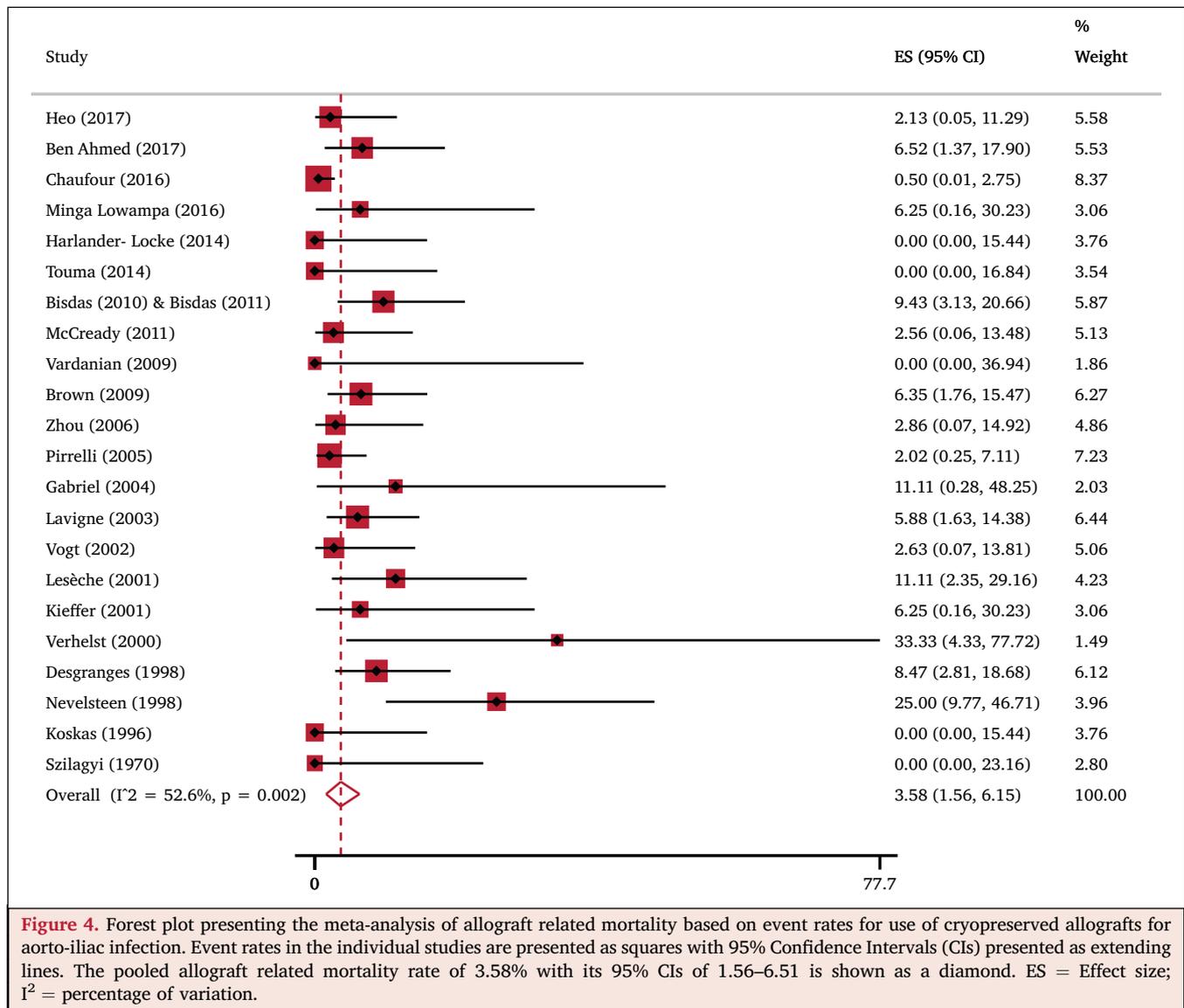
To anticipate the disadvantages of synthetic and venous grafts, allografts have been used for *in situ* arterial reconstruction. Fresh allografts have been mainly abandoned because of high dilatation rates over the time.³⁰ Conversely, cryopreserved allografts taken from dead donors have gained popularity, because they have better collagen preservation and mechanical stability and they do not affect the viscoelasticity of muscular arteries and the wall structure of elastic arteries.¹ Their main cryopreservation action appears to diminish the immune response induced by fresh arterial allografts, thus improving their behaviour after grafting.¹ Among their main advantages is that they are less prone to infection, require only a short surgical duration, and are



associated with low morbidity and mortality.³⁶ Furthermore, cryopreserved allografts are processed so that they do not require blood group matching, they can be pre-selected to match the size of the recipient's aorta and branches and they generally include visceral, renal, and hypogastric side branches, which can be used for bypass to renal and visceral vessels.³⁰ Limitations of the technique include that a pre-defined, dedicated, and very detailed protocol of tissue harvesting is mandatory. Furthermore, careful use of cryoprotectants, freezing temperatures, controlled freezing rate,³¹ temperature storing, thawing, and washing before implantation are crucial. Moreover, allografts usually require several parts to be connected, anastomoses should be tension free, side branches should be ligated securely when not needed, and sufficient tissue debridement in the area before implantation should be performed meticulously to avoid reinfection.³⁶ Lastly, although allografts are soaked in antibiotics during their preparation, patients should receive long-term antibiotic therapy after implantation.¹ However, it should be highlighted that antibiotic soaking of allografts is a prophylactic measure, which is not part of the long-term antibiotic treatment of the initial infection, which duration depends on many other factors, such as the type of the initial

infection and the results of the per-operative microbiological samples.

Among the patient related adverse event predictors after the implantation of cryopreserved allografts, studies have highlighted the important role of type 1 diabetes mellitus, American Society of Anesthesiology class 4, advanced age, chronic renal insufficiency, emergency surgery, and coronary heart disease.¹ Furthermore, the bacteriological virulence and clinical severity of the native or secondary graft infection presentation are directly related to mortality.¹ Moreover, differences in the underlying cause of aortic infection (primary aortic infection vs. prosthetic graft infection vs. aorto-enteric fistula) and surgery urgency (urgent vs. elective, ruptured vs. intact) have also been identified as potential factors contributing to the heterogeneity of published results.³¹ These differences are mainly responsible for the diversity of the reported mortality rates among the eligible studies. The present meta-analysis has estimated a pooled 30 day mortality rate of 15%, ranging from a minimum of zero mortality as reported by Vardanian *et al.*⁴ up to 39% as reported by Chaufour *et al.*,²⁶ in which abdominal aortic endograft explantation for infection was high risk and associated with graft-enteric fistula in one



third of the cases. Interestingly, there was no late mortality resulting from allograft related complications in a study by Brown *et al.*² Proposed adjunctive techniques to improve outcomes after cryopreserved allograft implantation include the support of large anastomoses with allograft strips, use of additional sealing with antibiotic impregnated fibrin glue, through and through suturing of the allograft side branch with polypropylene suture, and omental wrapping.³¹

An important issue with the use of allografts is degeneration of the allograft material. Mechanisms of cryopreserved allograft degeneration include aortic wall injury and immune related tissue damage during cryopreservation. Interestingly, fractures seem to be more frequent below $-150\text{ }^{\circ}\text{C}$,¹ although other studies support that cryopreserved protocols at $-80\text{ }^{\circ}\text{C}$ and $-150\text{ }^{\circ}\text{C}$ did not have a significant influence on early mortality or the post-operative complication rate.⁴⁶ Furthermore, mechanical injury of the crystallised allograft prior to thawing, during intra-operative manipulations or during clamping of the thawed allograft is also implicated in allograft degeneration.³¹ This

degeneration might be responsible for the late adverse events, including rupture, disruption, and pseudoaneurysm. The present meta-analysis has estimated a pooled pseudoaneurysm formation in approximately 3%, perianastomotic rupture and allograft disruption in less than 6%, while allografts dilated in 5% of cases. These rates might vary significantly from study to study and might be related to the technique of the cryopreservation on diminishing the antigenicity of allografts.²⁹ As the risk of wall rupture and degeneration is very high following incorrect manipulation, one of the most recent studies¹ suggested that the cryopreservation technique should include viral and bacteriological screening of the harvested allografts, immersion in antibiotic solution, freezing to $-140\text{ }^{\circ}\text{C}$, and storing in vapour phase nitrogen until defrosting in the operating room. Of note, it has been proposed that cellular components of the vessel wall are able to trigger the immunological reaction and as a result, allografts should not be considered weakly antigenic. This might have clinical implication because the cryopreservation technique does

not guarantee complete antigenicity clearance and blood group matching alone might not be entirely appropriate.⁵⁰

The opportunity to offer *in situ* revascularisation after aortic infection is highly attractive, but it may be hampered by the potential for re-infection. In a study by Nevelsteen *et al.*,⁴¹ the authors reported three cases of re-infection in 25 patients. Interestingly, Lehalle *et al.*³⁵ reported four fatal cases of rupture within the third month after implantation of a cryopreserved allograft and a fifth allograft related death a long time later. All of their allograft rupture deceased patients had aorto-enteric fistula (AEF) as first presentation. They hypothesised that a large tissue involvement and complete debridement is not always possible in these “high grade infections” and this is responsible for a continuous degeneration of the native aortic wall, which is in proximity to the allograft suture line.

Although this meta-analysis is the first to analyse data, from a pool of 31 articles and more than 1 300 patients, on cryopreserved allografts for aortic arterial reconstruction, some limitations should be reported. Firstly, the level of evidence of the included studies is low. However, this is inevitable because of the rarity of the condition and because only small series have been published so far. Furthermore, most of the studies were retrospective in nature and information on whether consecutive patients were finally included is lacking. As a result, the possibility for selection bias may exist. What is more, although publication bias was only statistically evident in a minority of the evaluated secondary outcomes, the potential publication of only favourable outcomes by some of the studies might have existed. Additionally, no separate results were provided for each one of the aortic pathologies among the eligible studies, because of a lack of reporting. Some clinical entities, such as AEF were more severe than others, such as low grade infections, leading to different results among the studies. However, the eligible studies did not report data separately for patients with vs. without AEF or native aorta vs. prosthetic graft infection and as a result, it is impossible to estimate pooled outcomes with AEF or type of infection as confounders. As distinction was not made between persistent or recurrent infection, no conclusion could be drawn about the effect of the type of infection on outcomes. Furthermore, differences among the eligible studies in the cryopreservation protocol, surgical technique, initial indication, severity of aorto-iliac infection, study sample characteristics, and definition of graft patency might explain part of the heterogeneity of the results. What is more, differences concerning medical treatment, including length of antibiotic therapy, as well as the systematic use of antifungal therapy are also of importance to explain the heterogeneity. As a result, more and better studies on the topic are needed to draw conclusions on the benefit of the technique.

CONCLUSION

In conclusion, use of cryopreserved allograft for arterial reconstruction after aorto-iliac infection appears to be safe

and durable. As no guidelines are clearly established concerning treatment of aorto-iliac infection, further studies, with a randomised control design comparing these methods might help in identifying the best method for treating this severe aortic pathology.

CONFLICT OF INTEREST

None.

FUNDING

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejvs.2019.03.003>.

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