

Hypothermic machine perfusion versus static cold preservation in kidney transplantation

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Abstract

Introduction

The adequate preservation of the allograft prior to kidney transplant is key for a good outcome after transplantation. Currently, there are two main methods: hypothermic machine perfusion and static cold preservation. The main objective of this summary is to compare both preservation systems.

Methods

We searched in Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach.

Results and conclusions

We identified 10 systematic reviews including 34 primary studies, of which 13 were randomized trials. We concluded preservation by hypothermic machine perfusion probably decreases the risk of delayed graft function and could lead to a slight increase in graft survival. However, there are no differences in patient survival between the two methods.

Problem

There is an imbalance between demand and availability of organs for kidney transplantation, so strategies to increase the latter are required. One of them is to address organ preservation, in order to optimize the state of the kidneys prior to transplantation and achieve better post-transplant results.

Both hypothermic machine perfusion and static cold storage are alternatives for graft preservation prior to transplantation. Hypothermic machine perfusion generates a continuous pumping of perfusion solution to the renal parenchyma, which provides nutrients

and oxygen, and removes toxins, theoretically decreasing damage derived from time of ischemia. Static cold is currently the most widely used method due to its greater availability, but the use of hypothermic machine perfusion has been increasing in recent years due to the change in donors profile, advances in technology and available perfusion solutions. It is relevant to determine which method is more effective in terms of post-transplant results.

Key messages

- Hypothermic machine perfusion probably decreases the risk of delayed graft function, might slightly improve survival of the graft at 1 year, but it makes little or no difference in the survival of the patient.
- It is not clear whether hypothermic machine perfusion decreases primary failure of the graft because the certainty of the evidence is very low.

Methods

To answer the question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos) using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies when it is possible, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We found 10 systematic reviews¹⁻¹⁰, including 34 primary studies¹¹⁻⁴⁴.</p> <p>This table and the summary in general, are based on the latter, since the observational studies did not increase the certainty of the evidence nor provide additional relevant information.</p> <p>Some systematic reviews also included animal studies, which were not considered in this summary of evidence⁵.</p>
<p>What types of patients were included*</p>	<p>Five trials only included donors with circulatory death^{22,25,26,42,44}; four trials only included brain-dead donors^{21,23,31,43}; two trials included donors with both circulatory and brain death^{12,20}; one trial included brain-dead patients and expanded donor criteria⁴¹, and one trial included patients with circulatory death, brain death, and expanded donor criteria²⁹.</p> <p>The average age of donors was 39.9 years for donors with circulatory death and 46.3 for donors with brain death.</p> <p>The average time of ischemia was 23.5 hours for kidneys receiving hypothermic machine perfusion, and 19.5 hours for static cold.</p>
<p>What types of interventions were included*</p>	<p>All trials compared hypothermic machine perfusion against static cold^{12,20,21,22,23,25,26,29,31,41,42,43,44}.</p> <p>The type of perfusion machine used to perform hypothermic perfusion varied between the different trials. One trial used Waters/ Gambro²², five trials used only Waters MOX100^{12,21,23,31,43}, four trials used ORP LifePort^{25,41,44,29}, one trial used only Gambro⁴² and one trial used Nikkiso APS-02²⁶. There is no information regarding the type of machine used in one trial²⁰.</p>

	The different preservative fluids used in static cold also varied between trials. Four trials used the Euro-Collins solution ^{12,20,21,31} , seven trials used a solution from the University of Wisconsin ^{22,26,29,41-44} and one used Marshall's solution ²⁵ . Only one trial did not specify which preservative solution for static cold was used ²³ .
What types of outcomes were measured	The trials measured different outcomes, which were grouped by the systematic reviews as follows: <ul style="list-style-type: none"> • Delayed graft function • Primary graft failure • Graft survival at 1 year • Survival of the patient at 1 year

* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

Summary of Findings

The information on the effects of hypothermic machine perfusion compared to static cold preservation is based on 13 randomized trials that included 2122 kidneys^{12,20-23,25,26,29,31,41-44}.

All trials measured delayed graft function (2122 kidneys), eight trials primary graft failure (1719 kidneys)^{20,22,26,29,31,41,42,44}, 10 trials graft survival at one year (2002 kidneys)^{20-23,25,29,31,41,42,44} and six survival of the patient at one-year (1622 kidneys)^{20,22,29,31,41,44}.

The summary of findings is as follows:

- Hypothermic machine perfusion probably decreases delayed graft function. The certainty of the evidence is moderate.
- It is not clear whether hypothermic machine perfusion decreases primary failure of the graft because the certainty of the evidence is very low.
- Hypothermic machine perfusion might slightly improve graft survival at 1 year, but the certainty of the evidence is low.
- Hypothermic machine perfusion results in little or no difference in survival of the patient at 1 year. The certainty of the evidence is high.

Hypothermic machine perfusion versus static cold preservation in kidney transplantation				
Patients	Patients undergoing a kidney transplant			
Intervention	Hypothermic machine perfusion			
Comparison	Static cold storage			
Outcome	Absolute effect*		Relative effect (95% CI)	Certainty of evidence (GRADE)
	WITH static cold storage	WITH hypothermic machine perfusion		
	Difference: patients per 1000			
Delayed graft function	430 per 1000	344 per 1000	RR 0.80 (0.70 to 0.92)	⊕⊕⊕○ ¹ Moderate
	Difference: 86 kidneys less (Margin of error: from 35 to 129 less)			
Primary graft failure	62 per 1000	57 per 1000	RR 0.91 (0.48 to 1.71)	⊕○○○ ^{1,2} Very low
	Difference: 5 kidneys less (Margin of error: from 32 less to 44 more)			
Graft survival at 1-year	797 per 1000	837 per 1000	RR 1.05 (1.00 to 1.11)	⊕⊕○○ ^{1,2} Low
Survival of the patient at 1 year	Difference: 40 kidneys more (Margin of error: from 0 to 88 more)		RR 0.99 (0.97 to 1.01)	⊕⊕⊕⊕ High
Patient survival at 1 year	938 per 1000	928 per 1000	RR 0.99 (0.97 to 1.01)	⊕⊕⊕⊕ High
	Difference: 10 kidneys less (Margin of error: from 28 to 9 more)			

Margin of error: 95% confidence interval (CI).
RR: Risk ratio.
GRADE: Evidence grades of the GRADE Working Group (see later).
 *The risk **WITH static cold storage** is based on the risk in the control group of the trials. The risk **WITH hypothermic machine perfusion** (and its margin of error) is calculated from relative effect (and its margin of error).
¹The certainty of evidence was downgraded one level because of risk of bias.
² The certainty of the evidence was downgraded two levels for imprecision, since the decision could vary at the extremes of the confidence interval. In the case of primary graft failure, two levels were downgraded by this factor, since the decisions at each end of the interval would be very different.

Follow the link to access the interactive version of this table ([Interactive Summary of Findings – iSoF](#))

About the certainty of the evidence

(GRADE)*

⊕⊕⊕⊕

High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.

⊕⊕⊕○

Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate.

⊕⊕○○

Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.

⊕○○○

Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.

* This concept is also called 'quality of the evidence' or 'confidence in effect estimates'.

† Substantially different = a large enough difference that it might affect a decision

Other considerations for decision-making

To whom this evidence does and does not apply

The evidence presented in this summary applies to kidney grafts from donors with circulatory death, cerebral death or expanded criteria.

Most of the donors and recipients were adults, so this evidence should be extrapolated with caution to the pediatric population. There was no distinction between sexes, so the results are applicable to both groups indistinctly.

About the outcomes included in this summary

The outcomes included in this summary are those considered critical for clinical decision making, according to the opinion of the authors. In general, they coincide with those presented in the systematic reviews identified.

Balance between benefits and risks, and certainty of the evidence

Hypothermic machine perfusion probably decreases delayed graft function in comparison with the static cold storage, with a moderate level of certainty. It might also slightly improve the survival of the graft at 1 year, but the certainty of the evidence is low. Additionally, there is little or no difference in the survival of the patient at 1 year.

No information was found on adverse effects for both graft preservation techniques, which is an important piece of information for decision-making.

Resource considerations

One systematic review² analyzed cost-effectiveness between the two alternatives, concluding there is not enough evidence to generate an appropriate economic model, so their results should be interpreted with caution. This review indicates that hypothermic machine perfusion is associated with an increase in the costs of the transplant program in comparison to static cold preservation, mainly derived from perfusion machine and supplies. However, the costs would be offset by the subsequent reduction in hospitalization and dialysis requirements associated with a lower incidence delayed graft function and longer survival of the graft.

What would patients and their doctors think about this intervention

Regarding the evidence presented in this summary, many clinicians should prefer the use of hypothermic machine perfusion, since it decreases delayed graft function and could improve its survival. However, due to the lack of information on cost-effectiveness, and uncertainty about adverse effects, some variability in decision-making can be anticipated.

Differences between this summary and other sources

The conclusions of this summary agree with those of the identified systematic reviews.

The Kidney Disease Improving Global Outcomes (KDIGO) guidelines⁴⁵, the Kidney Disease Outcomes Quality Initiative (KDOQI)⁴⁶ and the Canadian Society of Transplantation⁴⁷ do not address the topic covered in this summary of evidence.

Could this evidence change in the future?

The probability that future research changes the conclusions of this summary is low, due to the certainty of the existing evidence, especially in relation to delayed graft function and survival of the patient.

We did not identify ongoing trials evaluating this question in the International Clinical Trials Registry Platform of the World Health Organization or systematic reviews in the International prospective register of systematic reviews (PROSPERO).

How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.

	van der Vliet J., 2001	Moers C 2009	Watson CJ 2010	Halloran P 1987	Matsuno N 1994	Heil JE 1987	Mozes M 1985	Jochmans I 2010	Alijani MR 1985
Hameed A.M. 2016	Green	Green	Green	Green	Green	Green	Green	Green	Green
Dikdan GS 2012	Green	Green	Green	Green	Green	Green	Green	Green	Green
O'Callaghan JM 2013	Green	Green	Green	White	Green	Green	Green	White	Green
Wight JP 2003	Green	White	White	Green	Green	Green	Green	White	Green
Bathini V 2013	Green	Green	Green	White	Green	White	White	White	White

An evidence matrix is a table that compares systematic reviews that answer the same question.

Rows represent systematic reviews, and columns show primary studies.

The boxes in green correspond to studies included in the respective revisions.

The system automatically detects new systematic reviews including any of the primary studies in the matrix, which will be added if they actually answer the same question.

Follow the link to access the **interactive version**: [Hypothermic machine perfusion versus static cold preservation in kidney transplantation](#)

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Notes

The upper portion of the matrix of evidence will display a warning of “new evidence” if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier.

After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

This article is part of the Epistemonikos Evidence Synthesis project. It is elaborated with a pre-established methodology, following rigorous methodological standards and internal peer review process. Each of these articles corresponds to a summary, denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos), whose main objective is to synthesize the body of evidence for a specific question, with a friendly format to clinical professionals. Its main resources are based on the evidence matrix of Epistemonikos and analysis of results using GRADE methodology. Further details of the methods for developing this FRISBEE are described here (<http://dx.doi.org/10.5867/medwave.2014.06.5997>)

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database

www.epistemonikos.org.

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