Comparative analysis of clinical efficacy and cost between University of Wisconsin solution and histidine-tryptophan-ketoglutarate

Objective—To compare University of Wisconsin solution (Viaspan), the universal standard for organ preservation, with histidine-tryptophan-ketoglutarate solution. An analysis of each solution, in reference to clinical trials with specific organs, is presented and assessed to find the efficacy of each in a clinical environment. Also to view each solution from an economical standpoint, and in the end develop an overall understanding of the key similarities and differences between each solution in order to assess appropriate use of each in a clinical setting.

Data Sources—A literature search was conducted by using PubMed, MEDLINE, BIOSIS, Embase, and other online data bases to find the most recent studies of University of Wisconsin and histidine-tryptophan-ketoglutarate solutions. Search terms included University of Wisconsin solution, histidine-tryptophan-ketoglutarate, preservation solution, cost analysis, biliary complication, and other related subjects.

Study Selection—Previous research was selected from the literature search to provide basic information on the 2 solutions and also to provide clinical examples of each solution and the efficacy of each with specific organs.

Data Synthesis—Information and published articles on the 2 solutions were gathered for descriptive and comparative purposes.

Conclusions—The 2 solutions appear equally effective in organ preservation. Each solution has its own organ-specific qualities, and each has different complications. The studies reviewed here indicate that the differences are minor and thus suggest that the 2 solutions are equally acceptable for clinical use. Of the 2 solutions, histidine-tryptophan-ketoglutarate costs less than University of Wisconsin solution. (*Progress in Transplantation.* 2008;18:166-172)

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Notice to CE enrollees:
A closed-book, multiple-choice examination after this article tests your ability to accomplish the following objectives:

1. Describe the advantages and disadvantages of University of Wisconsin (UW) solution compared with histidine-tryptophan-ketoglutarate (HTK)
2. Understand the evidence for the safe use of UW solution and HTK for organ preservation.
3. Recognize that both UW solution and HTK are comparable and equally sufficient for use as preservation solutions

University of Wisconsin (UW) solution is the current worldwide standard for the perfusion and preservation of abdominal organs. UW solution has a low osmolarity and contains colloid and free radical scavengers (glutathione, allopurinol, and adenosine).[1] Recently a preservation solution known as histidine-tryptophan-ketoglutarate (HTK) was approved by the US Food and Drug Administration for preservation of the liver, kidneys, pancreas, and heart. HTK was originally developed in the 1970s by Bretschneider for cardioplegia. HTK has a lower osmolarity than UW solution, a lower concentration of electrolytes, and a strong histidine buffer system that helps increase the osmotic effect of mannitol.[2] In recent years, some clinical trials of the 2 solutions have been done, and some organ procurement organizations have switched from UW solution to HTK. In this article, we examine recent studies that compared the 2 solutions and seek to provide evidence for the safe use of each in the clinical area of organ preservation.

In recent years, discussion has increased about the new preservation solution HTK and its abilities in organ preservation as compared with UW solution. HTK has many advantages over UW solution. Each solution has its own advantages with specific organs. The question

lies in which solution will provide the best overall results from a clinical and economic standpoint.

Convenience of Use

Certain medications must be added to UW solution before its use. These additives are necessary for the effective use of UW solution, and once the medication has been added, the solution must be used within approximately 24 hours. As a result, some UW solution is occasionally wasted when complications occur during organ recovery after the medication has been added. HTK does not require any additives and is ready to use upon opening. Time is saved when HTK is used because preservation coordinators are not required to medicate each liter bag individually. Second, HTK comes packaged in 1-L, 2-L, and 5-L bags, whereas UW is packaged only in 1-L bags. This packaging also makes recovery of organs easier. First, fewer materials are needed to travel with, and second, fewer bags have to be coordinated in the operating room.

Because of the presence of colloid, UW solution has a very high viscosity (6.2 cP). HTK, relying on a histidine buffer system, lacks colloid and thus has a viscosity (2.0 cP) similar to that of water. This low viscosity provides quicker perfusion and also eliminates the need for pressurized perfusion. Organs can be flushed by gravity alone, including back-table flushing.[3]

Volume and Cost

As mentioned previously, HTK has a viscosity similar to that of water. Because it has a much lower viscosity than UW solution, a much higher volume of HTK than UW solution would be recommended to perfuse to the same extent. The product label recommends a volume of 10 to 12 L for HTK, whereas the recommended volume for UW is only 6 to 8 L.[4] Fridell et al[2] also stated that the lower viscosity of HTK required a larger volume of solution; however, other studies[5,6] have shown that although HTK does require a larger volume, the difference is very small. In their clinical study with pancreas transplantation, Agarwal et al[5] found no significant difference in volume used between the 2 solutions. They found a 0.5-L difference in their analysis of 400 organ procurements. In another study on adult human liver transplantation, Mangus et al[6] found similar results. In their trial, the livers preserved with HTK received an average of 0.6 L more preservation solution than did those preserved with UW solution. These trials suggest that although HTK has a much lower viscosity than UW solution, HTK does not necessarily require as large an increase in volume used as directed or initially thought.

The current cost per liter of UW solution is $282.39. Penicillin G, dexamethasone, insulin, and mannitol are all added to UW solution before use. The current total cost of these additives is $18.28, which brings the total cost per liter of UW solution to $300.67. HTK does not require any additives, so no costs must be added to the price per liter. The current price per liter of HTK is $181.12, which gives a total savings per liter of solution of $119.55 when HTK is used. As stated previously, a slightly larger amount may be needed when perfusing with HTK; however, the volume increase may not be as much as recommended or initially presumed. Even with the greater volume of HTK needed, the overall cost should decrease.

Multiple Organs

UW solution has become the primary solution for preservation of abdominal organs, whereas solutions such as Celsior are often used for cardiac preservation. HTK has been clinically tested and approved for preservation of both thoracic and abdominal organs. Clinical trials indicate that HTK is comparable to both UW solution and Celsior and is equally effective for organ preservation. As Ringe et al[4] stated, even though HTK and UW solution are used as multiple organ perfusion solutions, they each contain organ-specific characteristics. The effectiveness of each solution on specific organs varies, and by reviewing the clinical trials on each organ, specific conclusions about the overall effectiveness of the solutions can be reached.

UW solution is also rarely used in cardiac perfusion; however, Celsior solution is the typical solution used for many cardiac transplants. HTK, on the other hand, provides a solution for both abdominal and thoracic procedures. UW solution contains a high level of potassium, which if entered into circulation of the blood stream can cause cardiac arrest in the patient.[7] HTK contains a very low amount of sodium and potassium and is a safer alternative. In a recent study[8] on rat hearts, researchers discovered that HTK could potentially support cardiac function when cold ischemia times reached as much as 8 hours. Evidence of these extended times in humans was not discovered during this literature study. In another study, HTK was found to be superior to UW solution in protecting endothelium-derived hyperpolarizing factor (EDHF) and thus in protecting against EDHF-mediated relaxation, which in turn would make HTK superior for cardiac preservation.[9]

HTK was originally developed for cardioplegia and has recently been approved for perfusion of abdominal organs as well. Various clinical studies have been performed to compare the efficacy of HTK against UW solution in human liver transplantations. Moray et al[10] found that each solution was equally effective in perfusion of the liver. In another study, Meine et al[11] also found no significant difference between the 2 solutions. Mangus et al[6] discovered slightly elevated median levels of aspartate aminotransferase, alanine aminotransferase, and total bilirubin after day 1 in the HTK group; however, each solution was similar thereafter and they

concluded that both solutions were equally effective. In a study[12] of 60 patients, no difference between outcomes of the 2 solutions was observed even when cold ischemia times exceeded 15 hours. For several reasons, which included the high risk of cardiac arrest with the use of UW solution because of its high level of potassium, Chan et al[3] suggested that HTK was, in fact, superior to UW solution. They also stated that because of the low viscosity of HTK, flushing of the hepatic artery at the back table could be performed by gravity alone. Pokorny et al[13] also found that they received better rinsing with HTK; however, they went on to state that this difference does not necessarily point to HTK's superiority over UW solution. Feng et al[14] also found promise in HTK and suggested that HTK was better than UW solution for hepatic microcirculation and that HTK causes less deterioration in the deformability of red blood cells.

HTK has also been approved for the preservation of kidneys, and HTK has been compared with UW solution for preservation of kidneys in clinical trials. Klaus et al[15] found that HTK and UW solution were equally effective for kidney preservation and transplantation. De Boer et al[16] also found that HTK was comparable to UW solution with respect to rates of initial nonfunction and graft survival of human kidneys. In a separate study, De Boer et al[17] stated that the initial nonfunction was not associated with the solution used but was dependent on the donor's age, donor's cause of death, retransplantation, and cold ischemia time, which further proved the comparability of HTK and UW solution in kidney preservation. In a slightly different study,[18] HTK was observed to be comparable to UW solution in kidney preservation when cold ischemia times were less than 24 hours; however, with extended cold ischemia times (beyond 24 hours) HTK was inferior to UW solution in regard to delayed graft function. This finding was observed in other studies with other organs; however, Agarwal et al[19] suggested that this finding may not be true. In their study, Agarwal et al[17] observed kidney function with cold ischemia times greater than 16 hours and stated that when cold ischemia time extends beyond 24 hours, HTK is not inferior and may lead to better protection against delayed graft function than UW solution provides. These studies show that HTK is also comparable to UW solution with regard to kidney preservation and transplantation.

Studies have also shown that HTK is adequate for use on the human pancreas. Fridell et al[2] had 100% patient and graft survival rates and found that HTK and UW were both sufficient for preservation and transplantation of the pancreas. In a larger study, Becker et al[20] also found that both solutions were equally effective and showed equivalent clinical results with no increase in rejection rate. Agarwal et al[5] found the same to be true but noted that UW solution did carry the risk of the formation of crystal deposits with perfusion, which will be discussed later. Potdar et al[21] stated that HTK appeared to cause more edema after aortic flush than UW solution caused, and their results showed a slightly higher rate of inflammation in the HTK group (5/16 HTK vs 4/17 UW). They concluded that HTK was still comparable to UW solution for preservation and transplantation of kidney allografts.[21] Thus, although UW solution may provide a very slight advantage in pancreas preservation and transplantation, HTK is still comparable and safe for use on the pancreas as well.

Agarwal et al[22] also looked at preservation of renal allografts with pulsatile perfusion to compare UW solution and HTK in that respect. They observed a total of 55 donors (30 HTK, 25 UW solution) that ended in 91 transplantations. Patient and graft survival rates were 98% in both groups, leading them to conclude that no clinical difference was apparent between kidneys perfused with HTK or UW solution with pulsatile perfusion.[22]

Cold Ischemic Time

An important aspect relating directly to graft function after transplantation is the cold ischemic time the organ goes through. With the introduction of UW solution, the length of cold ischemic time grew drastically. Various studies have been conducted to compare the efficacy of HTK with the efficacy of UW solution at various cold ischemia times. In their study on kidneys, Roels et al[18] found little difference between graft function with UW solution and HTK when the cold ischemia times were less than 24 hours; however, when cold ischemia times surpassed the 24-hour window, the rate of delayed graft function for HTK increased to 50% whereas that for UW solution remained comparatively low at 23.9%.

In another study on kidney allografts, Agarwal et al[19] found that although it had previously been suggested that HTK was inferior to UW solution at longer ischemic times, they found no difference between the 2 solutions. They concluded that HTK was as effective as UW solution even with prolonged cold ischemia times extending beyond 24 hours. In a follow-up study on pancreas transplantation, they found that with an average cold ischemic time of 9 hours, HTK and UW solution were comparable for graft function.[5] Therefore, although some studies have shown that HTK is inferior when cold ischemia times reach 24 hours, evidence suggests that HTK has the potential to be just as effective as UW solution, even with these extended ischemic times.

Complications

In addition to being slightly stronger on specific organs, each solution also holds the potential for various complications. The complications associated with UW solution are closely correlated with its additives

and high viscosity, whereas the complications often seen with HTK are correlated with its lack of some of those additives.

Regarding the antioxidative additives in each solution, UW solution tends to be superior. Allopurinol and glutathione are each present in UW solution; however, the short half-life and auto-oxidative properties of the glutathione may limit its effects.[7] The mannitol in HTK is said to provide antioxidative abilities; however, Semmelmann et al[7] suggested that its effects may also be limited. Therefore, both solutions contain antioxidative substances that may be limited in function, but each solution is comparable to the other in clinical trials.

Another additive of UW solution is insulin, which promotes anabolic growth and was considered to aid in the regeneration of grafts.[3] However, in liver transplantation with rat livers, insulin was associated with increased ischemic injury and decreased graft survival rate.[3] Thus, the lack of insulin in HTK alleviates any such complications with graft survival when perfused with HTK.

One major issue that has arisen with the use of UW solution is biliary complications. In their study of 60 liver donations, Chan et al[3] found a higher late biliary complication rate in the group with organs preserved with UW solution; however, the difference in complication rates between organs preserved with UW solution and organs preserved with HTK were not significant. Ringe et al[4] also showed that UW solution had limitations in regard to biliary complications and suggested that HTK protected better against biliary complications. In their study of 39 donors, Avolio et al[1] found similar results in the HTK and UW groups. They found a total of 5 biliary complications: 3 in the UW group and 2 in the HTK group, thus again giving statistically insignificant results. In another study,[11] Meine et al found the opposite results: HTK was associated with a higher incidence of biliary complications. Meine et al[11] suggested that these results could have been related to the older age of patients in the HTK group or to other variables such as ischemia time, hypotension, and vasopressor use. As was true with overall efficacy, when cold ischemia times were short, the incidence of biliary complications did not differ significantly between the 2 solutions.[14] Although the difference was not statistically significant in most studies, HTK solution appears to have an advantage over UW solutions in protection against biliary complications.

Another problem with UW solution is the formation of crystal deposits when stored at temperatures below freezing. UW solution contains specific colloids to aid in stabilization of the cell membrane. These macroparticles, however, may lead to the accumulation of the crystal deposits previously mentioned.[5] The UW solution requires an inline filter to help with this problem. Chan et al[3] saw these results in their study, which showed that crystals formed at subzero temperatures in the UW solution. Tullius et al[23] found similar results at freezing temperatures but also suggested that particles have been seen in UW solution stored at 2°C to 8°C (the temperature range recommended by Viaspan, the manufacturer).

Finally, UW solution seems to be better at preventing edema. Semmelmann et al[7] stated that UW solution had a greater potential to prevent tissue edema than did HTK. In their study on the pancreas, Potdar et al[21] also found that all the organs preserved in HTK were more edematous than organs preserved in UW solution. Becker et al[20] found the same to be true in their study and suggested that the greater volume of HTK needed for perfusion may be the cause of the greater risk of edema in those organs. As previously mentioned, the large volume of HTK may not be entirely necessary, thus lowering this risk of edema.

Patient Care

An interesting discovery during our research involved the patients' quality of life and the overall length of time spent in the hospital with the use of a specific solution. As reported earlier, flushing can occur at a faster rate with the less viscous HTK solution, and thus those surgeries are often completed more quickly. Duration of hospital stay for HTK patients is often shorter than that for UW patients, as well. Klaus et al[15] found this to be true and stated that the shorter hospitalization period may be directly correlated with a faster surgical recovery. Chan et al[3] found the same to be true in their study of live donor liver transplants. They found that operation time and hospital stay were both shorter in the HTK group than in the UW group. Agarwal et al[19] took these findings a step further to show that the quality of life of patients in the HTK group was higher than the quality of life in the UW group according to the Karnofsky Performance Status Scale. These findings suggest that HTK not only has the potential for more efficient procedures but may also allow quicker recovery and better quality of life after the procedure.

Summary

UW solution has been the standard preservation solution for abdominal organs, but recently HTK has shown promise in preservation of both abdominal and thoracic organs. In many aspects, HTK is much easier to use clinically than UW solution. It is less viscous and thus perfuses easier, and it is also packaged in 1-L, 2-L, and 5-L bags compared with the 1-L bag packaging of UW solution. The larger bags provide easier transportation and easier use in the operating room. HTK also seems to be superior to UW solution from a financial standpoint. When comparing the current price of UW solution and its additives with the current

price of HTK, we found that HTK is cheaper by an amount of $119.55 per liter of solution. The necessity of mixing additives with UW solution also places it at a higher risk of being wasted because once the additives are added, the solution must be used within a short period. HTK does not require additional components, so it is both easier to use (ready when opened) and it eliminates a great amount of waste.

From a preservation standpoint, HTK and UW solution seem to be comparable and equally effective. As mentioned previously, HTK is sufficient for both thoracic and abdominal procedures. Through clinical trials, HTK has shown substantial promise with heart preservation. As for the liver and kidneys, HTK is as effective as UW solution and in some cases better results were seen with the HTK solution. UW solution appears to maintain slightly better results with pancreas preservation but HTK remains comparable in this area as well. The majority of clinical trials lead to the fact that when cold ischemia times are kept below 24 hours, HTK and UW solution are equally effective for organ preservation. The discrepancy arises when the cold ischemia time extends beyond 24 hours. When this occurs, some trials showed a decrease in the results of the HTK groups. Thus it often seemed as though UW solution was superior to HTK when the cold ischemia time was greater than 24 hours; however, in 1 study[19] HTK seemed to be equally effective at longer cold ischemia times.

Each solution also holds its own complications. Both solutions have antioxidative components that were comparable across various trials. UW solution also contains insulin, which may aid in regeneration but also increases the chance of ischemic injury and thus lowers the graft survival rate.[3] The additives in the UW solution also lead to the risk of crystal formation, which makes an inline filter necessary when perfusing with UW solution. Biliary complications are also higher when UW solution is used. Although the results were very similar and often are not statistically significant, HTK seemed to protect better than UW solution against biliary complications. Also, when cold ischemia times were low, biliary complications were less frequent in both groups. Finally, UW solution protects better against edema. In various studies, HTK-preserved organs seemed more edematous than those treated with UW solution. According to Becker et al,[20] this difference may be due to the greater volume of HTK needed for perfusion. But as other studies[5,6] showed, it may not be necessary to perfuse with a much greater volume of HTK than UW solution. These findings may alleviate one of the causes of edema when HTK is used.

We also found that surgical recovery and hospital length of stay may be shorter when organs are preserved with HTK. Results of 1 study[19] also suggested that the patients' quality of life was better when HTK was used than when UW solution was used.

From a financial standpoint, HTK seems to have an advantage over UW solution with its lower price and its lower amount of waste. Clinically, both solutions appear to be equally effective, with each holding its own slight advantages and disadvantages. In short, it appears that both solutions are comparable and equally sufficient for use as preservation solutions.

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CE Test

Test ID 4000-J54: Comparative analysis of clinical efficacy and cost between University of Wisconsin solution and histidine-tryptophan-ketoglutarate

Learning objectives: 1. Describe the advantages and disadvantages of University of Wisconsin (UW) solution compared with histidine-tryptophan-ketoglutarate (HTK) 2. Understand the evidence for the safe use of UW solution and HTK for organ preservation 3. Recognize that both UW solution and HTK are comparable and equally sufficient for use as preservation solutions

1. Which is correct about University of Wisconsin (UW) solution?
a. It is the current worldwide standard for the perfusion and preservation of thoracic organs.
b. It has a high osmolarity.
c. It is colloid free.
d. It contains free radical scavengers.

2. Which is correct about histidine-tryptophan-ketoglutarate (HTK)?
a. It is not approved by the Food and Drug Administration for thoracic organ preservation.
b. It has a weak histidine buffer system.
c. It was originally developed for cardioplegia.
d. It has no advantages over UW solution.

3. Compared with UW solution, which is correct about HTK?
a. HTK is packaged only in 1-liter (L) bags.
b. HTK has a higher osmolarity.
c. HTK has a higher electrolyte concentration.
d. HTK does not require any additives.

4. What is the viscosity of HTK?
a. 2.0 cP
b. 2.6 cP
c. 4.0 cP
d. 6.2 cP

5. Which is correct about the viscosity of UW solution?
a. Its viscosity eliminates the need for pressurized perfusion.
b. Its viscosity provides quicker perfusion than HTK.
c. Its viscosity is similar to water.
d. Its viscosity is very high.

6. What perfusion volume is recommended by the product label for HTK?
a. 2 to 4 L
b. 6 to 8 L
c. 10 to 12 L
d. 14 to 16 L

7. When HTK is used instead of UW solution, what is the total savings per liter of solution?
a. $18.28
b. $119.55
c. $181.12
d. $282.39

8. Which is correct about cardiac preservation?
a. HTK was reported to be superior to UW solution in protecting against relaxation mediated by endothelium-derived hyperpolarizing factor.
b. UW solution is frequently used.
c. HTK is not used because of its high potassium content.
d. UW solution is safer than HTK because of its very low sodium and potassium content.

9. Which is correct about the efficacy of HTK against UW solution in human liver transplantation?
a. Mangus et al discovered slightly elevated median total bilirubin levels after one day in the UW solution group.
b. Feng et al suggested that UW solution causes less deterioration in red blood cell deformability.
c. Moray et al found that each solution was equally effective in liver perfusion.
d. Chan et al suggested that UW solution was superior to HTK.

10. Which is correct about HTK compared with UW solution for preservation of kidneys?
a. De Boer et al found that UW solution was inferior to HTK with respect to rates of initial graft nonfunction.
b. Klaus et al found that HTK and UW solution were equally effective.
c. HTK is not approved for the preservation of kidneys.
d. De Boer et al found that HTK solution was superior to UW solution with respect to graft survival rates.

11. Which is correct regarding the additives in HTK compared with UW solution?
a. HTK tends to be superior regarding antioxidative additives.
b. Complications associated with UW solution are closely correlated with its additives.
c. Allopurinol is present in HTK.
d. Insulin in HTK promotes anabolic growth and graft regeneration.

12. Which is correct about complications of UW solution compared with HTK?
a. UW solution is associated with crystal deposit formation when stored at temperatures below freezing.
b. Biliary complications are higher when HTK is used.
c. HTK protects better against edema.
d. The insulin in HTK is associated with increased ischemic injuries.

Test answers: Mark only one box for your answer to each question. You may photocopy this form.

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My expectations were met	❑	❑
This method of CE is effective for this content	❑	❑

The level of difficulty of this test was: ❑ easy ❑ medium ❑ difficult

To complete this program, it took me _____ hours/minutes.

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If applicable: State(s) of licensure _____
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