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Cost of preventing variceal rebleeding with transjugular intrahepatic portal systemic shunt and distal splenorenal shunt

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Abstract

Background and aims—We examined the cost and cost effectiveness of distal splenorenal shunt (DSRS) and transjugular intrahepatic portosystemic shunt (TIPS) in the prevention of variceal rebleeding.

Subjects—Participants in randomized controlled trial comparing DSRS to TIPS.

Methods—Quality of life (QOL) measured using SF-36 preceding randomization and yearly thereafter. Cost utility analysis was performed using Data Treeage ®. Costs for both in- and out-patient events and interventions were obtained for each patient. Costs using coated stents were estimated using different rates of stenosis. Incremental cost effectiveness ratios (ICERs) were determined at 1, 3 and 5 years.

Results—The average yearly costs of managing patients after TIPS and DSRS over 5 years were similar, \$16,363 and \$13,492 respectively. Cost of TIPS for surviving patients exceeded the cost of DSRS at years 3 and 5 but not significantly. ICERs per life saved favored TIPS at year 5 (\$61,000). If coated rather than bare stents were used the cost-effectiveness of TIPS increased slightly.

Conclusions—TIPS is as effective as DSRS in preventing variceal rebleeding and may be more cost effective. TIPS, in all aspects, is equal to DSRS in the prevention of variceal rebleeding in patients who are medical failures.

1. Introduction

Variceal bleeding is one of the most serious complications of portal hypertension occurring in one third of patients with cirrhosis (1). Although outcome from variceal bleeding has improved

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there is still significant morbidity and mortality associated with each episode of bleeding (2, 3). Patients with variceal bleeding can be managed with either pharmacologic or endoscopic therapy to prevent rebleeding. However, 20–30% of patients will rebleed despite these therapies leading to variceal decompression as the only effective alternative (4,5).

A surgically created shunt, such as the distal splenorenal shunt (DSRS), has been considered the most effective method for preventing variceal rebleeding (6–10). More recently variceal decompression can also be performed less invasively by placing a stent within the liver that connects the portal vein to the hepatic vein (transjugular intrahepatic portosystemic shunt-TIPS) leading to decompression of the entire portal system and prevention of rebleeding (6,11–14). Although TIPS may be the preferred approach in compensated and decompensated patients due to availability and efficacy (6,11), it is unknown whether TIPS is as cost effective as shunts.

The costs associated with use of medical therapy vs. TIPS in the prevention of rebleeding have been investigated using a modeling approach. Total annual costs with TIPS were slightly greater than with endoscopic therapy but the incremental cost effectiveness ratio (ICER) per variceal bleed prevented favored the TIPS treatment strategy in one report whereas in another report band ligation plus a beta-blocker dominated all other forms of therapy (13,15). The difficulty with both of these modeling studies is that the outcome of the analysis was dependent upon the assumptions chosen about the bleeding risk with each form of therapy. Hence it would be beneficial to obtain outcome and associated cost data from a controlled trial with data obtained prospectively. In the recently completed and published controlled trial comparing TIPS to DSRS such data was obtained (6). The goal of this analysis was to compare the cost and cost effectiveness of these two approaches.

2. Methods

2.1 Patients and statistical calculations

Details of the study are in the recently published report describing a prospective randomized controlled clinical trial for patients with Child-Pugh class A and B cirrhosis who had variceal rebleeding refractory to medical therapy (6). 73 patients received a DSRS and 67 a TIPS with a mean follow-up ranging of 46 ± 26 months. Data collected from the participating sites was entered and stored in an Oracle data base. Data management was conducted using Oracle and data analyses performed using SAS and JMP software. All analyses were performed on an intent-to treat basis. Comparisons of continuous variables were performed using either Student's t-test (i.e. for Health Related Quality of Life (HRQL) data) or its nonparametric equivalent the Wilcoxon rank sum test (i.e. for cost data). All reported P-values are two-sided; P-values of 0.05 or less were considered statistically significant.

2.2 Health Related Quality of Life and Utilities

Utility measures health on a scale from 0 to 1 with 0 representing death and 1 perfect health and is used as the effectiveness measure in cost utility analyses (16). The SF-36 (Short Form – 36 questions) was used to measure quality of life (QOL) and was completed at randomization and annually thereafter and provided HRQL data (17–19). Preference based health utility indices were derived from the SF-36 in a method known as the SF-6D (20,21). The SF-6D was used in this study to derive utility data for patients. Mean per patient scores were calculated at 1, 3 and 5 year time intervals. Utility data for patients who died was a sum of their mean SF-6D results for the period they were alive and a utility figure of 0 for the remaining time in the analysis for the deceased patients.

2.3 Cost Utility Model

Cost utility models (CUA) were developed in Treeage Data® Version 4.0 to investigate the cost effectiveness of DSRS versus TIPS in patients participating in this clinical trial. Three different CUAs were constructed at 1, 3 and 5 year time intervals. Patients were divided into those who survived to these time horizons and those who did not. The analysis was from the U.S. healthcare perspective, using cost data in the form of 2004 dollars. It included the cost of all relevant direct healthcare utilization but excluded indirect (productivity) costs. Utility data was calculated via the SF-6D from SF36 HRQL data. Results were expressed as ICERs in the form of cost in dollars per quality adjusted life years (QALYs) saved. Discount rates of 3% were used for both costs and outcomes, as recommended by the U.S. panel for cost effectiveness in health and medicine (22).

A probabilistic sensitivity analysis (PSA) was conducted to investigate the effect on cost-effectiveness, when costs and the probabilities of outcomes were varied, in the form of Monte Carlo simulation (n=1,000) (23). Beta distributions were used to vary HRQL and the probability of dying within a particular time horizon. Empirical costs were assigned log-normal distributions. Mean ICERs were calculated along with their 95% Confidence Intervals. Acceptability curves were established to determine the probability of one procedure being cost effective at different cost effectiveness thresholds (24).

2.4 Healthcare Utilization

Initial Procedure—All patients were hospitalized for their initial procedure. A Diagnostic Related Group (DRG) of either 191 or 192 (Pancreas, Liver and Shunt Procedures with or without complications respectively) was coded to our patients' randomization hospitalization dependent on their length of stay and complications during hospitalization. National Medicare reimbursements for these DRGs were used from 2003 and inflated to 2004 costs using the medical care inflation index (22). The proportion of patients assigned to DRG 191 and 192 were respectively 87% at cost of \$27,725 and 13% at cost of \$9,970. This was then used to calculate a standard DSRS procedure cost. There is no specific DRG associated with TIPS. The actual costs derived from the Cleveland Clinic's cost accounting database were accessible to the DIVERT project team, based in the clinic. The mean actual cost for the randomization hospitalization was derived for the DSRS group and the TIPS group and the percentage difference calculated. This percentage difference was used to calculate a similar difference in DRG costs for TIPS versus DSRS.

Hospitalizations—The DRG codes assigned to study patients who were hospitalized in the follow-up period were derived from the cost accounting databases of the 5 participating centers. The patients were also asked if they had been hospitalized elsewhere since they were last seen and that data was collected. National Medicare reimbursements per DRG, were used to assign costs to hospitalizations. Professional codes were derived in the form of in-patient current procedural terminology (CPT) codes. These were joined to the US national faculty costs contained in Medicare's 2004 version of the Physician Fee Schedule. A median professional cost was derived for each DRG and these were used to assign professional costs to the hospitalizations that occurred outside of the study centers. Hospitalization costs were calculated as the sum of the DRG and professional CPT cost.

Out- Patient Visits—All out-patient CPTs for our study population were derived from the cost accounting systems of our 5 participating centers. At study visits, the nurse coordinator identified if the patients had hospitalizations or out- patient hospital visits, laboratory tests, angiograms, ultrasounds (including those post procedure), endoscopies and re-interventions. These were compared to the CPTs derived from the cost accounting databases and those not already accounted for were coded and cost estimated.

Re-interventions—If a patient was hospitalized for the purpose of receiving a re-intervention, the DRG costs coded to the reason for admission were used. When a DRG was not coded, a code of 192 and its relevant cost was assigned. If the re-intervention was performed as an out-patient then the costs associated with appropriate CPTs codes were used for both re-dilatation and re-stenting. The additional cost of the actual stent (\$1,500) was added to the re-stenting procedure. Follow-up costs were obtained for abdominal Doppler ultrasound and assumed to occur at 6 weeks and 3 months post re-intervention. Any CPT data associated with these re-interventions already collected was deleted to eliminate any double costing.

2.5 Varying stenosis rates using coated stents

Sensitivity analysis was performed on differing re-intervention rates with the use of coated rather than the bare metal stents. It was assumed that patients who required re-stenting would maintain the DIVERT average of 1.5, 2.1 and 2.2 stents respectively in the 1, 3 and 5 years follow-up period with the same follow-up costs as used in the DIVERT study. A cost of \$3,000 was assumed for coated stents and that all TIPS patients would initially incur the additional cost of 1 coated stent instead of 1 bare metal stent (i.e. additional \$1,500).

2.6 Laboratory Data and Medications

CPTs associated with laboratory data were derived from the study centers' cost accounting database in the same fashion as out-patient and in-patient CPTs and cost calculated using Medicare's fee schedule. Detailed lists of medications consumed by the study participants were not collected in this study. It was assumed that standard medications were used to treat ascites and encephalopathy from the month of diagnosis to the month of liver transplant, death or last study contact. Standard monthly costs for lactulose, spironolactone and furosemide were assigned to patients with these complications.

2.7 Costs for alcoholics vs. non-alcoholics

Patients were divided into alcoholics and non-alcoholics based on their status at study inclusion. Total median per patient costs with interquartile ranges were determined for each group.

3.0 Results

The initial cost of the two procedures was \$21,607 for TIPS and \$28,734 for DSRS. Table 1 contains the costs associated with patients who were alive at each time point. The costs associated with each procedure are shown for in-patient care, out-patient care, laboratory tests and medications during the 5 years of follow-up. Fifty-eight percent of TIPS patients and fifty percent of DSRS patients required re-hospitalization during the first year of follow-up and the hospitalization costs for TIPS were significantly greater than those for DSRS. At year 3 and 5 more patients with TIPS had required re-hospitalization but the hospital costs for each group of patients were not significantly different (Table 1). Out-patient costs at years 1, 3 and 5 were always significantly more for the TIPS patients as compared to the DSRS patients. Total costs were greater for TIPS as compared to DSRS at years, 3 and 5 but the differences were not significant (Table 1). We also determined the costs associated with patients who died during the study with different time horizons (Table 2). Hospitalization, out-patient and total costs at year 5 were significantly greater for the TIPS group as compared to the DSRS group (Table 2). Lastly, we determined the costs at 5 years for alcoholics vs. non-alcoholics. Costs were greater for alcoholics vs. non-alcoholics but there was no difference between TIPS and DSRS in the two populations. However, DSRS was significantly more expensive in the alcoholic as compared to the nonalcoholic population (Table 3).

Utility was assessed using the SF-6D. Baseline mean SF-6D scores with 95% CIs were 0.64 [0.61–0.68] and 0.62 [0.58–0.65] for TIPS and DSRS patients respectively. Shown in Table 4

are the utilities for both the surviving and patients who died during each time interval. There were no significant differences in utility at any of the time points. Shown in Table 5 are the results of the cost utility analysis using probabilistic sensitivity analysis. TIPS was on average both more costly and more effective (in terms of quality adjusted life years (QALYs)) than DSRS at all time points but using a threshold of \$100,000/QALY indicated that TIPS was only moderately cost effective by 5 years post initial treatment. The acceptability curves at years 1, 3 and 5 are shown in Figure 1 with ICERs indicated for each time point of analysis. At year 5 the probability that the ICER would be < \$50,000 was ~50% whereas the probability was ~65% if < \$100,000 was chosen as being cost effective. However, the wide confidence intervals obtained for the ICERs suggests that TIPS is not significantly more cost effective than DSRS at any point in follow-up (Table 4).

The development of coated stents has reduced the stenosis rate of TIPS significantly. This should have an impact on follow-up costs. Therefore, we performed a sensitivity analysis to determine if the use of coated as opposed to bare stents would influence the cost effectiveness of TIPS vs. DSRS. In Table 6, the actual stenosis rates observed at 1, 3 and 5 years in the study using bare stents are shown. We then estimated the cost of using coated stents assuming stenosis rates of 15%, 30% and 50%. There was a small cost savings using the coated stents when the stenosis rate was 15% or 30% and an additional cost if the stenosis rate was 50%. However, the changes in the ICERs were small and didn't make TIPS significantly more cost effective if coated as opposed to bare stents had been used in the study.

4.0 Discussion

This is the first study to assess prospectively the resource utilization of preventing rebleeding from esophageal varices treated by variceal decompression using either a TIPS or DSRS. We feel this study provides a unique view of the cost of caring for patients over a 5 year period with well compensated cirrhosis who bled from varices. In addition, QOL data was obtained prospectively on all patients. Because this data was obtained prospectively no assumptions were needed as to incidence of rebleeding, etc. and thus the results are a more accurate reflection of the costs associated with these procedures and subsequent follow-up care than are the numbers obtained from the use of modeling.

Although the initial direct cost of DSRS was greater than for TIPS, in the first year hospital costs and out-patient costs associated with TIPS were significantly greater than for DSRS patients reflecting the need for monitoring and re-intervention to maintain TIPS patency (6). This need for monitoring and re-intervention did not disappear over time as the out-patient costs for TIPS increased over the 5 year period of observation (Table 1).

One way to reduce the need for re-intervention is the use of coated stents. When using coated stents 13% of patients required re-intervention during the first 300 days of a trial (14). We estimated the differences in costs and outcomes for the TIPS cohort when coated stents were theoretically used for all TIPS procedures. As can be seen in Table 5 the greatest reduction in overall costs for the TIPS cohort was seen with a 15% restenosis rate but the differences were small. Part of the reason that overall cost reduction were not greater is the additional cost to all patients of the coated as compared to the bare stents. Hence, the cost of TIPS using coated stents over a period of 5 years is still likely to be greater than the cost of a DSRS.

Costs of management of variceal bleeding have been determined or estimated in a number of studies. In one study the one year direct costs of managing patients who bled from varices with endoscopic therapy were \$13,197 for sclerotherapy and \$9,696 for variceal band ligation (25). In two reports using modeling the estimated annual direct costs for preventing rebleeding using variceal band ligation or TIPS were \$16,600 to \$23,459 and \$26,275 to \$30,900

respectively (13,15). In the current study the median annual direct costs for survivors at 5 years were for TIPS = \$16,363 and for DSRS = \$13,492. Part of the difference between this and the above reports reflects the failure in the latter to consider that the cost of treating these patients is greatest in the first year and then steadily declines over time as can be seen in Tables 1 and 2. In addition, by preventing rebleeding in ~90% of patients with portal decompression the need for hospitalization due to variceal rebleeding was reduced to a greater degree than previously appreciated and this would result in a cost savings over a 5 year period. Lastly, the current study only included patients with well compensated liver disease whereas in the modeling reports there was no restriction on the type of patients enrolled and patients with more advanced disease are likely to incur higher costs.

Although the direct costs were less for DSRS patients than for those receiving a TIPS, the effectiveness in terms of QALYs favored those receiving a TIPS. This occurred because HRQL data in QALYs was always greater for the TIPS group due to the survival advantage in terms of months that was seen at an early stage in the study. Over the total span of the study there was no survival advantage (6) but this early difference affected all of the calculations. An ICER of < \$50,000/QALY would be considered a cost effective strategy, whereas an ICER of \$50,000–\$100,000/QALY would be considered moderately cost effective. Therefore, TIPS was more expensive than DSRS at each time point and its benefits were not sufficient to make it moderately cost effective compared to DSRS until 5 years post procedure. Based on acceptability curves the probability that TIPS at years 1 and 3 of follow-up could be cost effective is low. The acceptability curves also suggest that even at year 5 TIPS has a probability of 0.5 to 0.65 of being moderately cost effective and thus may be marginally more cost effective than DSRS (Figure 1).

Patients with alcoholic liver disease have been shown to have a worse prognosis following DSRS than non-alcoholic patients have (26) and the current study stratified patients to control for this variable. No difference between TIPS and DSRS was found in these two populations as far as survival, rebleeding rates (6) or cost (Table 3) are concerned. However, the cost of DSRS in the alcoholic population was significantly greater than in the non-alcoholic patients. The reasons for this are unclear but resumption of drinking is known to increase the likelihood of liver dysfunction and this would add to cost of management (27).

There are several limitations to this study. When this study was begun the only tool available to assess QOL was the SF-36. Subsequently a Liver Disease Questionnaire (CLDQ) has been developed to assess QOL in patients with liver disease. The SF-36 has been compared to the CLDQ in a number of studies. Reasonably good correlations between the SF-36/SF-6D and CLDQ for most domains were found and similar changes in both tools with disease progression have been reported (28–30). We, therefore, feel the SF-36 is a suitable tool for calculating cost-effectiveness of the two procedures. This analysis applies only to the USA as we used Medicare costs but it does give relative costs that can be used world-wide. Lastly, indirect costs were not measured so only the costs associated with management were determined.

This study has shown that both TIPS and DSRS are effective therapies in the prevention of rebleeding from varices, being 10.5% and 5.5% respectively with excellent survival (6). In the current report these initial observations are extended and show that TIPS is somewhat more expensive than DSRS. However, the cost effectiveness of the two approaches is similar and with the use of coated stents TIPS approaches being more cost-effective. Given the efficacy, safety, and cost effectiveness of TIPS and the increasing lack of surgeons who can perform portasystemic shunts well, TIPS should be considered the procedure of choice to treat recurrent variceal bleeding refractory to medical therapy in patients with well compensated cirrhosis.

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Abbreviations

TIPS	transjugular intrahepatic portosystemic shunt
DSRS	distal splenorenal shunt
ICER	incremental cost effectiveness ratio
QOL	quality of life
HRQL	health related quality of life
CUA	cost utility models
QALYs	quality adjusted life years
PSA	probabilistic sensitivity analysis
DRG	diagnostic related group
CPT	current procedural terminology

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Appendix

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Figure 1.

Acceptability curves of incremental cost effectiveness thresholds based on Monte Carlo simulation (n=1,000) of DSRS vs TIPS in the control of refractory variceal bleeding in patients with Child's Class A or B cirrhosis

Table 1
Costs associated with patients who survived the different time horizons studied in the cost utility analyses

Patients who survived and were allocated to TIPS						Patients who survived and were allocated to DSRS					
	# Pts Alive	% Alive Patients with resource use	Median	25% IQR	75% IQR	# Pts Alive	% Alive Patients with resource use	Median	25% IQR	75% IQR	P *
Initial Procedure	67	100%	\$21,607			73	100%	\$28,734			
Hospitalization by 1 Yr	62	58%	\$21,731	\$15,371	\$33,621	64	50%	\$14,738	\$8,134	\$22,145	0.036
Hospitalization by 3 Yr	55	78%	\$31,867	\$16,217	\$49,902	52	67%	\$24,709	\$13,373	\$50,926	0.30
Hospitalization by 5 Yr	44	84%	\$38,578	\$16,140	\$66,674	47	68%	\$28,945	\$14,800	\$57,723	0.40
Out Patient Visits by 1 Yr	62	98%	\$4,157	\$1,658	\$5,832	64	98%	\$1,238	\$551	\$1,866	<0.001
Out Patient Visits by 3 Yr	55	98%	\$6,510	\$4,532	\$10,470	52	98%	\$3,009	\$1,779	\$5,307	<0.001
Out Patient Visits by 5 Yr	44	98%	\$10,053	\$5,724	\$14,351	47	100%	\$4,374	\$2,546	\$7,821	<0.001
Lab Data by 1 Yr	62	92%	\$173	\$104	\$208	64	97%	\$173	\$104	\$208	0.900
Lab Data by 3 Yr	55	96%	\$277	\$143	\$392	52	98%	\$277	\$208	\$346	0.48
Lab Data by 5 Yr	44	93%	\$346	\$255	\$519	47	100%	\$346	\$173	\$485	0.98
Medications by 1 Yr	62	27%	\$660	\$510	\$720	64	34%	\$456	\$345	\$720	0.19
Medications s by 3 Yr	55	38%	\$1,860	\$630	\$2,100	52	52%	\$1,368	\$720	\$1,680	0.47
Medications 5 by Yr	44	39%	\$2,100	\$1,336	\$3,104	47	57%	\$2,100	\$840	\$2,280	0.51
Total by 1 Yr	62	100%	\$35,691	\$26,049	\$51,174	64	100%	\$36,886	\$30,335	\$45,415	0.42
Total by 3 Yr	55	100%	\$54,084	\$35,138	\$78,092	52	100%	\$46,664	\$35,244	\$71,514	0.32
Total by 5 Yr	44	100%	\$70,527	\$37,165	\$100,711	47	100%	\$48,796	\$38,579	\$74,903	0.18

* Statistical Differences are calculated using the non parametric Wilcoxin Rank Sum Test IQR-interquartile range

Table 2 Costs associated with patients who died within the different time horizons studied in the cost utility analyses

Patients who died following allocation to TIPS						Patients who died following allocation to DSRS					
	# Pts Dead	% Dead Patients with resource use	Median	25% IQR	75% IQR	# Pts Dead	% Dead Patients with resource use	Median	25% IQR	75% IQR	P*
Initial Procedure	67	100%	\$21,607			73	100%	\$28,734			
Hospitalization by 1 Yr	5	60%	\$45,689	\$29,267	\$48,817	9	56%	\$16,003	\$8,837	\$40,710	0.18
Hospitalization by 3 Yr	12	83%	\$37,548	\$27,479	\$54,711	21	76%	\$23,551	\$16,003	\$48,051	0.07
Hospitalization by 5 Yr	23	91%	\$45,689	\$30,943	\$61,696	26	77%	\$27,615	\$16,777	\$49,792	0.02
Out Patient Visits by 1 Yr	5	80%	\$2,528	\$559	\$3,794	9	56%	\$1,600	\$495	\$11,737	0.90
Out Patient Visits by 3 Yr	12	92%	\$3,495	\$2,712	\$3,959	21	81%	\$2,059	\$1,222	\$5,713	0.33
Out Patient Visits by 5 Yr	23	96%	\$6,682	\$3,493	\$11,195	26	81%	\$2,259	\$1,432	\$4,706	0.0052
Lab Data by 1 Yr	5	80%	\$69	\$29	\$121	9	44%	\$138	\$77	\$173	0.14
Lab Data by 3 Yr	12	92%	\$138	\$69	\$277	21	76%	\$207	\$121	\$268	0.49
Lab Data by 5 Yr	23	96%	\$242	\$69	\$303	26	77%	\$242	\$173	\$381	0.61
Medications by 1 Yr	5	20%	\$698	/	/	9	44%	\$487	\$429	\$525	0.16
Medications s by 3 Yr	12	67%	\$799	\$360	\$1,169	21	52%	\$1,410	\$518	\$1,960	0.22
Medications 5 by Yr	23	70%	\$870	\$360	\$2,348	26	58%	\$1,714	\$528	\$1,960	0.38
Total by 1 Yr	5	100%	\$52,505	\$21,754	\$72,881	9	100%	\$42,418	\$28,734	\$52,883	0.95
Total by 3 Yr	12	100%	\$58,293	\$49,607	\$73,719	21	100%	\$52,167	\$38,130	\$74,269	0.43
Total by 5 Yr	23	100%	\$74,267	\$57,583	\$95,087	26	100%	\$54,975	\$40,274	\$80,777	0.0336

* Statistical Differences are calculated using the non parametric Wilcoxon Rank Sum Test

Table 3
Comparison of costs in alcoholics vs. non-alcoholics after 5 years follow-up

	N	Survived to 5 yrs	Median Cost	25 th Quantile	75 th Quantile	P
Total Alcoholics	80	43	\$66,951	\$47,987	\$94,680	0.0059 *
Total Non Alcoholics	60	42	\$48,828	\$33,647	\$76,719	
TIPS Alcoholics	37	18	\$74,267	\$58,293	\$94,043	0.125
DSRS Alcoholics	43	25	\$59,381	\$42,418	\$96,196	
TIPS Non Alcoholics	30	22	\$61,288	\$34,301	\$102,275	0.1170
DSRS Non Alcoholics	30	20	\$47,196	\$32,157	\$59,871	
TIPS Alcoholics	37	18	\$74,267	\$58,293	\$94,043	0.2028
TIPS Non Alcoholics	30	22	\$61,288	\$34,301	\$102,275	
DSRS Alcoholics	43	25	\$59,381	\$42,418	\$96,196	0.0124 *
DSRS Non Alcoholics	30	20	\$47,196	\$32,157	\$59,871	

p using Wilcoxon Rank Sum Test.

* denotes significance at p< 0.05.

Table 4
Utility data derived from the SF-6D for patients who survived and died

Randomization	# who survived	# with SF6D	Median SF-6D	25% IQR	75% IQR	Median Survival (months)	HRQL for time horizon
TIPS - 1 Yr	62	60	0.637	0.587	0.764	12	0.637
DSRS - 1 Yr	64	59	0.639	0.551	0.717	12	0.639
TIPS - 3 Yr	55	53	0.630	0.584	0.774	36	1.89
DSRS - 3 Yr	52	49	0.662	0.571	0.753	36	1.986
TIPS - 5 Yr	44	42	0.657	0.577	0.762	60	3.285
DSRS - 5 Yr	47	45	0.646	0.576	0.763	60	3.23
Randomization	# who died	# with SF6D	median SF-6D	25% IQR	75% IQR	Median Survival	HRQL for time horizon
TIPS - 1 Yr	5	2	0.56	0.500	0.684	2.4	0.112
DSRS - 1 Yr	9	3	0.573	0.398	0.693	1.8	0.086
TIPS - 3 Yr	12	9	0.619	0.530	0.740	16.4	0.846
DSRS - 3 Yr	21	15	0.573	0.510	0.658	16.7	0.797
TIPS - 5 Yr	23	20	0.622	0.565	0.741	32	1.659
DSRS - 5 Yr	26	19	0.574	0.527	0.664	21.7	1.036

A lower utility score indicates a poorer quality of life

Table 5
Results of the cost utility analyses using probabilistic sensitivity analysis.

Time Horizon	Strategy	Cost	Incremental Cost	Effect (QALY)	Incremental Effect (QALY)	Cost/Effect	Mean ICERs with 95% C.I.s (\$/QALY)
1 Year	DSRS	\$41,941		0.5747		\$72,979	
	TIPS	\$44,772	\$2,831	0.6026	0.0279	\$74,298	\$101,470 [– \$64,740,\$549,946]
Time Horizon	Strategy	Cost	Incremental Cost	Effect (QALY)	Incremental Effect (QALY)	Cost/Effect	Mean ICERs with 95% C.I.s (\$/QALY)
3 Years	DSRS	\$57,921		1.6297		\$35,541	
	TIPS	\$67,760	\$9,839	1.6998	0.0701	\$39,864	\$140,357 [–92,678, \$394,382]
Time Horizon	Strategy	Cost	Incremental Cost	Effect (QALY)	Incremental Effect (QALY)	Cost/Effect	Mean ICERs with 95% C.I.s (\$/QALY)
5 Years	DSRS	\$66,685		2.441		\$27,319	
	TIPS	\$84,033	\$17,348	2.722	0.281	\$30,872	\$61,737 [– \$78,518,\$503,721]

QALY = quality adjusted life year.
ICER – incremental cost effectiveness ratios
C.I.- confidence intervals

Table 6
Re-intervention rate in TIPS patients (n=67) using 15%, 30% and 50% stenosis rates

Time Horizon	# Pts with stenosis	Total # Stents	Mean Number Re- stents/patient	Re-stent Rate	ICER
1 Year – Actual	31	35	1.1	46%	\$101,470
3 Year – Actual	43	56	1.3	64%	\$140,357
5 Year – Actual	49	71	1.4	73%	\$61,737
	Assumed # Pts with stenosis	Assumed Total # Stents	Assumed Mean Number Re- stents/patient	Difference in per patient re-stent cost when compared to the base case scenario	ICER when using the new costs of coated stents and reduction in followup costs
1 Year – 15% Restenosis	10	11	1.1	Per patient costs increase by \$395	\$115,627
3 Year – 15% Restenosis	10	13	1.3	Per patient costs decrease by \$634	\$131,312
5 Year – 15% Restenosis	10	14	1.4	Per patient costs decrease by \$1,684	\$55,744
1 Year – 30% Restenosis	20	22	1.1	Per patient costs increase by \$1,301	\$148,100
3 Year – 30% Restenosis	20	26	1.3	Per patient costs decrease by \$392	\$145,949
5 Year – 30% Restenosis	20	28	1.4	Per patient costs increase by of \$230	\$61,655
1 Year – 50% Restenosis	34	37	1.1	Per patient costs increase by \$2,509	\$191,398
3 Year – 50% Restenosis	34	44	1.3	Per patient costs increase by \$2,161	\$171,184
5 Year – 50% Restenosis	34	48	1.4	Per patient costs increase by \$1,299	\$66,359