Preliminary Analysis - TAU
Surgical ablation for atrial fibrillation (Modified Maze procedure)

Lonny Erickson, Ph.D; James Brophy MD, Ph.D.

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Request

On June 19 2007, TAU received an email request from Gary Stoopler to evaluate a request from the chief of cardiac surgery, Dr. Benoit de Varennes, via the Operating Room Product Evaluation Committee, to evaluate the purchase of equipment and supplies for the surgical treatment of atrial fibrillation during cardiac surgery which was already planned for other associated conditions.

Patient population:

Cardiac surgery patients with atrial fibrillation (chronic or paroxysmal) associated with valvular heart disease, estimated 30 per year.

Specific intervention and technologies proposed:

Surgical ablation for atrial fibrillation- evaluation of 2 techniques:

1) radiofrequency (Medtronic CardioBlate BPLP)
2) cryogenic (ATS Medical Cryocath System)

Costs

The Medtronic proposal includes 20 units of the Cardioblate BP2 ($3,200 / unit) and 10 units of the Monopolar model ($2,000 / unit) for a total estimated cost of $84,000. The manufacturer is proposing to supply the MUHC with $64,000 of savings in-kind.

The ATS proposal is for $2,500 per unit. The manufacturer proposes a $20,000 of saving in-kind.

I: EFFECTIVENESS OF PROPOSED INTERVENTIONS

Key publications:

1. **The Medical Advisory Secretariat of the Ontario Ministry of Health and Long-term care** published a report in March 2006 entitled *Ablation for Atrial Fibrillation,* which considered catheter based therapies as well as those performed during surgery. (Available at www.health.gov.on.ca/english/providers/program/mas).

This literature review concluded regarding ablation in addition to heart surgery versus heart surgery alone in patients with atrial fibrillation that:

'*It is clear that patients with drug-refractory AF who are undergoing concomitant heart surgery benefit significantly from surgical ablation in terms of long-term freedom from AF, without substantial additional risk compared with those who have only open heart surgery.'* (p.37)

However, they also note that:

'*There is insufficient evidence at this time supporting the use of surgical ablation for patients with drug-refractory, lone AF.'* (p.37)

Three other pertinent publications were mentioned in the Ontario MAS report:

I: Systematic review: Khargi et al, 2005

This review found that those treated with ablation + radiofrequency energy or cryoablation had similar rates of postoperative sinus rhythm conversion rate or 30-day mortality rate compared with AF patients treated for with the standard surgical Cox maze procedure . While this review included information on over 3,800 patients, all studies were cohort studies. 98% of patients underwent concomitant surgery (usually mitral valve repair or replacement).

II: NICE overview on radiofrequency ablation for atrial fibrillation (NICE, 2005)

This assessment concluded that there was adequate evidence to support the use of radiofrequency surgical ablation in association with other cardiac surgery. 7 studies were included in this review (1 RCT). They noted that this technique was easier to perform than the original Cox maze procedure.

III: NICE overview on cryoablation for atrial fibrillation (NICE, 2005)

This assessment included 6 non-randomized studies, and concluded that there is limited but promising evidence that cryoablation is an effective and safe energy source for ablation in patients with atrial fibrillation undergoing other cardiac surgery.

Newer publications:

Some pertinent newer publications have been identified, for example a case series (73 patients) which found no difference in outcome between radiofrequency or cryotherapy treated patients undergoing mitral valve surgery (Gehi et al., 2006).

II: ESTIMATED IMPACT OF PROPOSED INTERVENTIONS

The following table examines the potential impacts on outcomes and costs of the use of surgical ablation (modified Maze procedure) for atrial fibrillation in cardiac surgery patients at the MUHC.

Table I: Relevant data from literature

Parameter	Value (source)	Best Estimate (expert opinion)
Clinical Outcomes		
outcomes of stroke	25% mortality([3]),	
probability of stroke for patients with AF		6%
overall rate of stroke (CVA)	0.5-1.6% post Maze([7])	6% for patients with AF
rate of pacemaker placement	4.9-5.8% post Maze ([7]) however so far at the MUHC, rate of pacemaker placement is 0/29 patients ([2]). However, this rate was 8% in a series of 24 patients at the ICM (Pagé P, conference abstract 2003)	
rate of AF		80% without Maze 20% post Maze
rate of bleeding	4.4-4.9% post Maze ([7])	4% with Maze 2% without Maze
Costs		
Average yearly cost of atrial fibrillation	3 307 Euros (France,[5]) $ 14 000 US, ([6])	
Average yearly cost of AF-related anticoagulation, (hemorrhagic complications and embolic events)	$ 1400 Cdn([4]) (1998 currency)	
% reduction in costs and hospitalizations from Maze Procedure	.: 84% reduction in hospital days 2 yrs postop, 75% reduction in hospital costs ([1])	
acute hospital cost per case of stroke	$ 11 611 CDN 1994-5, (10)	
Utilities		
post- stroke	25% death= 0 50% minor=0.8 25% major= 0.4	avg 0.5 (incl death,minor, major, (8))
AF (well)	0.98 (9)	

CVA= cerebrovascular accident

Table 2 : Estimated costs and consequences of using this therapy on 25 patients per year at the MUHC

Parameter	Value- without surgical ablation	Value- with proposed use of surgical ablation procedure	Difference per year
Scenario: 25 patients treated with surgical ablation			
Impact on outcomes			
n (%) of patients with AF	20 (80%)	5 (20%)	-15 patients
n of patients with AF and stroke	1.2	0.3	-0.9 patients
n of deaths patients with AF and stroke	0.3 patients/year	0.075 patients per year	-0.045 patients
1-3 days hospitalized per year, per patient ([1])	3.5	0.5	-3 days per patient/year= -75d/yr.
DC conversions, per patient ([1])	1	0.5	-0.5 per patient per year
Costs			
Total Costs for procedure ([2])	0$	$62 500- $80 000	+$62 500- $80 000
cost per avoided case of AF (excluding all savings)		$ 4 167- $5 333	
Avoidance of 1 case of stroke (acute hospitalization)	0$	$ 12 000	-$ 12 000
Savings from avoided anticoagulation, hemorrhagic complications, embolic events with AF	0$	?	not included
savings from avoided antiarrhythmic medication	0$	?	not included
Savings from avoided hospitalization costs for AF	0$	Based on Swedish Study (1): 3days per pt/yr @ $ 1000 per day= $ 75 000 2days pp/yr= $ 50 000 1 day pp/yr=$ 25 000	potential reduction of $ 25- 75 000
Savings from avoided DC conversions	0$	?	not included

Abbreviations: AF= atrial fibrillation

Note: Mortality was expected to be equal in both arms (5%) and was excluded.

Key Points:

For an investment of $ 60-80 000 to use this procedure in 25 patients yearly at the MUHC, the following benefits could be expected:

Outcomes

- the prevention of AF in 15 patients
- prevention of a stroke in one patient

Costs:

Potential savings for the MUHC could include the following:
In the 15 patients for whom AF was prevented:

- reduction in hospitalizations due to AF estimated at 1-3 days of hospitalization per patient per year= $25-$ 75 000
- reduction in DC conversions 0.5 per patient per year= 12.5 fewer per year
- reduction in anticoagulation therapy (INR), in 15 patients (not estimated)
- reduction in antiarrhythmic medications in 15 patients (not estimated)

In the one patient for whom a stroke was avoided:

- $ 12 000 in acute hospital costs avoided (this excludes all long-term costs)

Cost-utility estimation:

The major impact on the gain of quality adjusted life years with this technique is expected to be the prevention of stroke. There are also quality of life gains to be expected in avoiding congestive heart failure but these are difficult to estimate. A major impact on cost would occur if hospitalization rates decrease as mentioned in the literature. Some conservative yet incomplete estimates can be made from available data.
Taking an average utility value following stroke of 0.5 and considering an average life expectancy of 10 years, prevention of 1stroke in the above example would result in a gain of 10y x 0.5= 5 QALY. This excludes any gain from avoiding 14 AF cases without stroke, and also long term costs and costs of avoided medications. As presented in the following table, this would give a very attractive cost per QALY even if no potential cost savings (i.e. from avoided hospitalization cost AF were included in the model (see discussion).

Cost of intervention (scenario)	QALY gain (prevented stroke only)	estimated cost per QALY
1: $ 80 000 (high cost of treatment, all savings excluded)	**5**	$ 16 000
2: $ 50 500 (low cost estimate for treatment, including acute hospital savings for 1 avoided stroke)	**5**	$ 11 000
3: $ 25 500, (Scenario 2, with 1 day of hospitalization avoided per patient treated @ $ 1000 per diem)	**5**	$ 5 100
4: $ 38 000, (Scenario 2, with 1 day of hospitalization avoided per patient treated @ $ 500 per diem)	**5**	$ 7 600
5: $ 500, (Scenario 2, with 2 days of hospitalization avoided per patient treated @ $ 1000 per diem)	**5**	$ 100

CONCLUSIONS

Effectiveness

- The benefits of surgical ablation of AF have been recognized in a recent, credible literature review.
- It is encouraging that the MUHC has previously used a similar technique (laser-) with success rates entirely compatible with those reported in the literature (>80%).
- The literature indicates that the two proposed techniques (cryogenic, radiofrequency) are both encouraging but insufficient to make conclusions regarding the superiority of either technique.

Impact

Based on currently available information, it seems that the use of surgical ablation of AF in patients already undergoing cardiac surgery at the MUHC can clinically reduce the prevalence of atrial fibrillation and this is likely to be associated with meaningful health benefits, Moreover, the attainment of these health benefits appears to be cost-effective.

Before considering any potential cost savings from avoided procedures related to AF, the estimated cost per avoided case of AF is estimated at $ 4 000 - $ 5 000. If 2 days of future hospitalization for AF were avoided per patient treated, the cost per avoided case of AF would drop to $ 1 500 - $ 2 000. This cost does not include other potential savings such as avoidance of a stroke or other interventions (i.e. DC conversion), so could potentially be lower.

Due to the previous experience using this type of technique at the MUHC, there is a high likelihood of attaining these positive results with the new technologies.

Recommendation

The above analysis suggests that the incorporation of this established technology is likely to provide meaningful health benefits at a very moderate cost. It must be stressed that this is a preliminary analysis and a complete literature search and analysis (involving Markov modeling) has not been performed. However the health benefits seem so large and the cost so low, that it is most unlikely that the completion of a more detailed analysis could substantially alter these conclusions. We will proceed with this more detailed analysis and will immediately alert you if the conclusions should change but feel it is important to rapidly circulate this preliminary report so as not to retard optimal decision making for MUHC patients. It must be recalled that this review has evaluated surgical AF techniques only in the population of patients already undergoing cardiac surgery for other conditions and is not applicable to the surgical treatment of lone AF.

References

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