Economic Analysis of **RF Transseptal Puncture**

NRG® Transseptal Needle

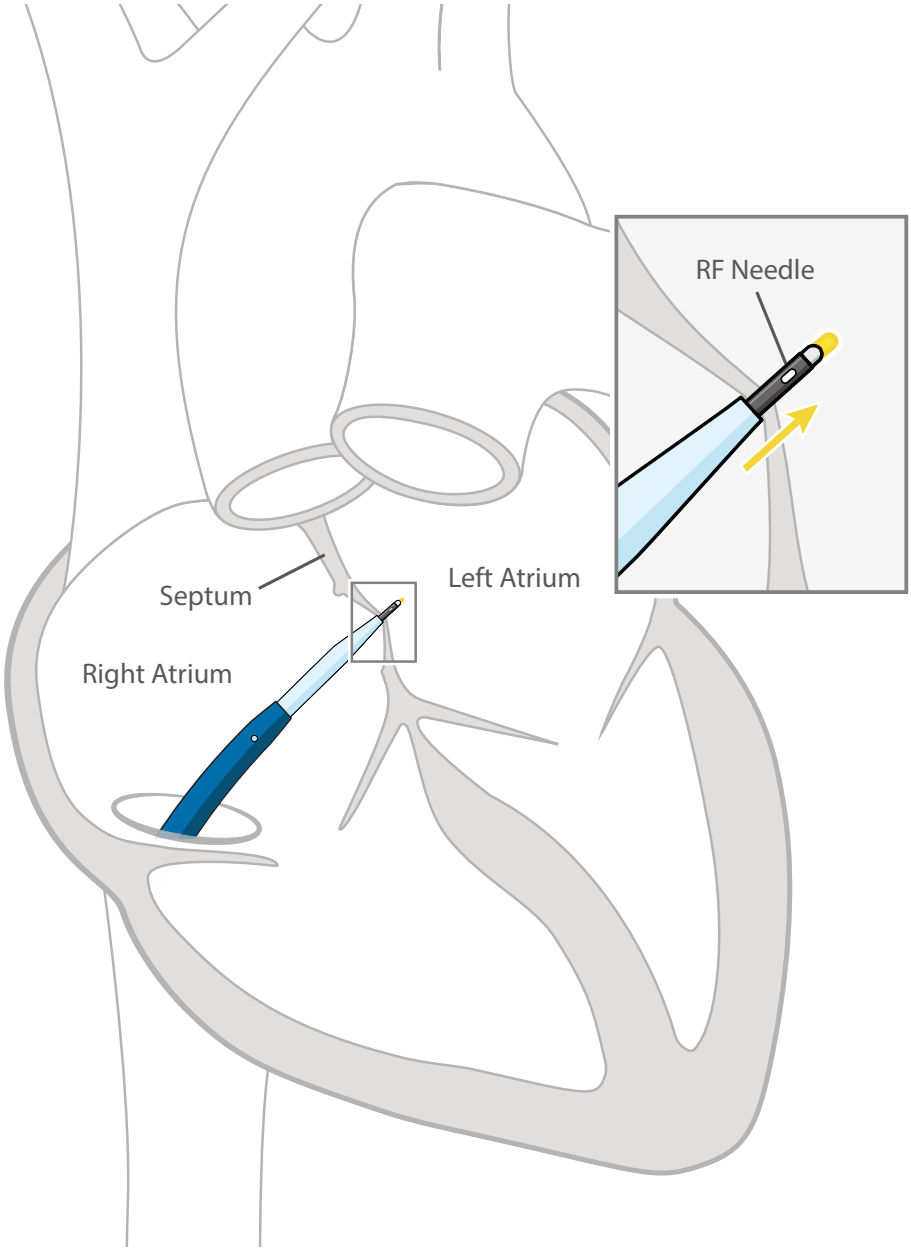
USA

Baylis MEDICAL

Save up to $1,856 per case

*in savings through improved clinical outcomes with use of Baylis Medical's RF transseptal puncture technology.**

* Refer to page 9 for analysis.



Executive Summary

Transseptal puncture is a well-known and widely-used procedure, providing percutaneous access to the left atrium of the heart.

Common cardiac procedures that are performed in the left side of the heart include:

- *Catheter ablation to treat cardiac arrhythmias*
- *Structural heart procedures such as transcatheter left atrial appendage occlusion and mitral valve repair*

Transseptal puncture has historically involved pushing a sharp, "mechanical needle" across the interatrial septum to gain left-heart access. Despite its common use, the transseptal puncture process can be associated with serious complications, such as cardiac tamponade. It can also be unpredictable and associated with procedure termination when the septum cannot be crossed, and time consuming.

The undesirable clinical events associated with catheter ablation procedures have been shown to add substantial incremental healthcare expenditures.

To overcome these shortcomings, a radiofrequency (RF) transseptal needle was developed. The NRG® Transseptal Needle uses a blunt-tipped electrode to deliver RF energy, allowing reliable, controlled access to the left atrium without needing to push a sharp, mechanical needle across the septum.

Clinical studies have highlighted the reliability and consistency provided by Baylis Medical RF needle transseptal puncture technology by demonstrating:

1. **Reduced rate of serious complications**
2. **Reduced rate of failed transseptal crossings resulting in procedure termination**
3. **Reduced procedure time**

These clinical benefits can translate into healthcare cost savings of up to $1,856 per case*

*Refer to page 9 for analysis.

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Background

Transseptal puncture is a well-known and widely-used procedure, providing percutaneous access to the left atrium of the heart. This enables performing common cardiac procedures such as:

- *Catheter ablation to treat cardiac arrhythmias*
- *Structural heart procedures such as transcatheter left atrial appendage occlusion and mitral valve repair*

Transseptal puncture has historically involved pushing a sharp, "mechanical needle" across the interatrial septum to gain left-heart access. Despite its common use, the transseptal puncture process can be:

- *Associated with serious complications, such as cardiac tamponade*
- *Unpredictable and associated with procedure termination when the septum cannot be crossed*
- *Time consuming*

A study led by researchers at Massachusetts General Hospital, Boston has shown that undesirable clinical events associated with catheter ablation procedures add substantial incremental healthcare expenditures.[1]

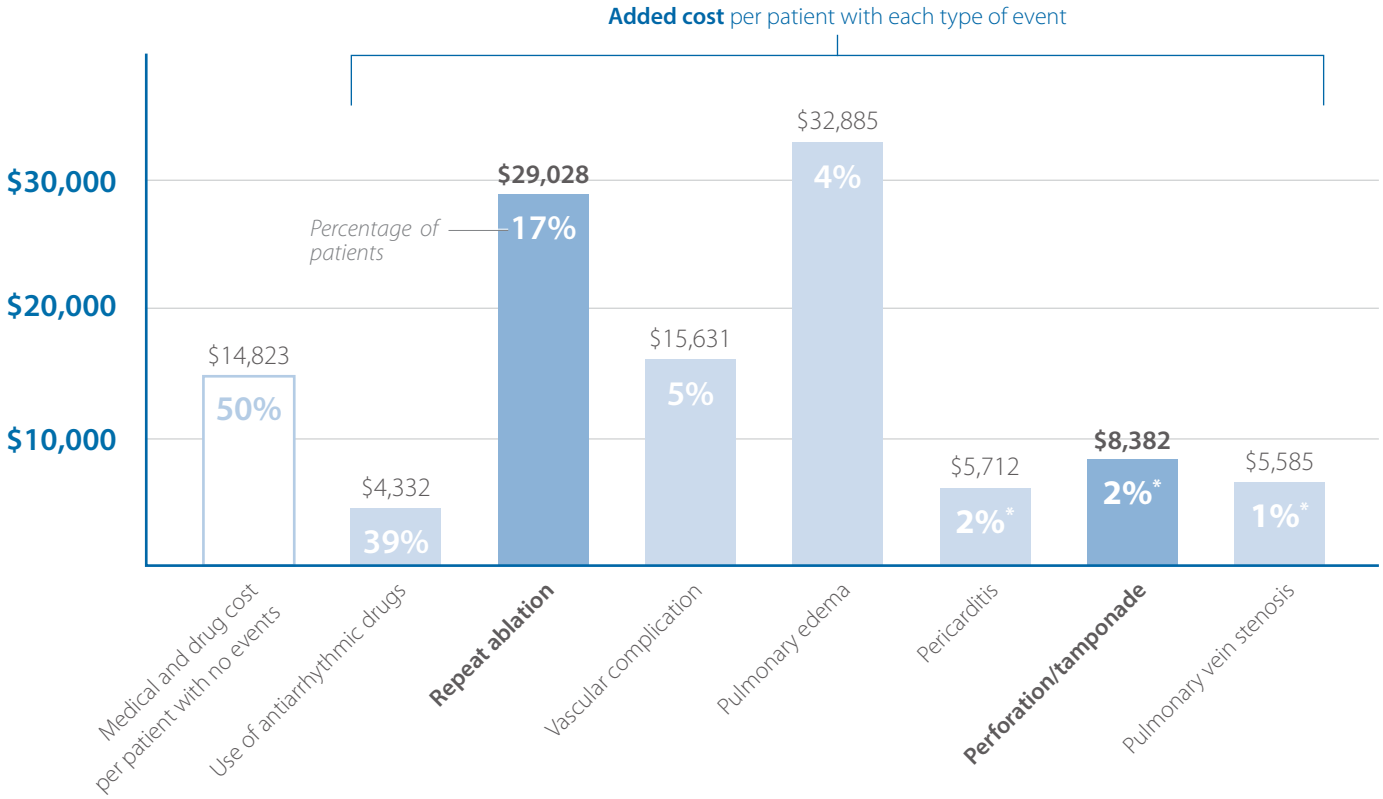

Figure: *Baseline cost in year after AF ablation and incremental cost of clinical events*

**Approximate percentages*

1. Mansour et al. Heart Rhythm Society (HRS) Scientific Sessions. 2016. [Abstract PO01-77]. Cost data from study of insurance-claims of 9,949 patients (2009-2012). http://www.heartrhythmjournal.com/issue/S1547-5271(16)X0004-5

Clinical Value of RF Transseptal Needles

Baylis Medical Company Inc. has developed radiofrequency (RF) transseptal needle technology.

The NRG® Transseptal Needle uses a blunt-tipped electrode to deliver a short and highly focused RF energy pulse, allowing a reliable, controlled puncture without needing to push through the septum using a sharp, mechanical needle.

Clinical studies *have demonstrated the value of RF transseptal needle technology:*

Reduce Rate of **Serious Complications**

- Cardiac tamponade is a serious complication associated with transseptal puncture
- It is a medical emergency and can be fatal
- Studies comparing mechanical and RF transseptal needles have shown that use of RF needles can lower the rate of cardiac tamponade by **up to 100%***[2,3]
- A randomized controlled trial showed that **27.8%** of mechanical needle cases required crossover to RF needle due to concern that further effort could lead to perforation of lateral wall[4]

Reduce Rate of **Failed Transseptal Crossings Resulting in Procedure Termination**

- When septum cannot be crossed, case is cancelled and patient is typically rescheduled for re-attempt at ablation procedure
- Studies comparing mechanical and RF transseptal needles have shown that use of RF needles can lower the rate of procedure termination by **up to 100%***[2,3]
- A randomized controlled trial showed that **27.8%** of mechanical needle cases required crossover to RF needle due to concern that further effort could lead to perforation of lateral wall[4]

Reduce **Procedure Time**

- Crossing the septum can be difficult and time consuming, prolonging the case and delaying the beginning of the therapeutic intervention
- It has been shown that use of the RF needle can lower the time to cross the septum by **up to 9 minutes**[3,4]

2. Jauvert et al. Heart Lung Circ. 2015

3. Winkle et al. Heart Rhythm. 2011

4. Hsu et al. J Am Heart Assoc. 2013. With RF needle available for crossover, no cases in this study resulted in cardiac tamponade or procedure termination.

** Based on an absolute reduction in incidence of up to 2% in study populations.*

Economic Value of Improved Transseptal Outcomes

*Avoiding undesirable clinical events during transseptal puncture can have **positive economic effects**:*

Cardiac Tamponade Cost	Repeat Ablation Cost	Procedure Time Cost
The incremental cost per event of cardiac tamponade to the healthcare system has been reported to be:	The incremental cost per event of repeat ablation to the healthcare system has been reported to be:	Literature has shown the cost per minute of time used in electrophysiology catheter ablation procedures to be:
$8,382 USD[1]	**$29,028 USD**[1]	**$105/minute** for procedural reimbursement **and** **$14/minute** for personnel fees[5]

1. Mansour et al. Heart Rhythm Society (HRS) Scientific Sessions. 2016. [Abstract PO01-77]. Cost data from 2009-2012.
5. Capone et al. PACE. 2015. Microcost analysis of procedure resource costs associated with catheter ablation of Wolff-Parkinson-White or left-sided concealed accessory pathway.

Summary of Economic Benefits of RF Needles

Cost savings *offered by Baylis Medical RF Transseptal Needles:*

Lower Rate of **Tamponade**	Lower Rate of **Procedure Termination**	Shorter, More Predictable **Transseptal Procedure Times**
Up to **$16,764*** per 100 cases	Up to **$58,056**** per 100 cases	Minimize time delays
$168 per case	**$581 per case**	**Up to $1,107† per case**

Total healthcare savings provided by improved clinical outcomes with use of RF transseptal puncture technology:

*Up to **$1,856** per case*

**Calculated as 2 x $8,382. Data from Jauvert et al. Heart Lung Circ. 2015 and Mansour et al. HRS Scientific Sessions. 2016.*

***Calculated as 2 x $29,028. Data from Jauvert et al. Heart Lung Circ. 2015 and Mansour et al. HRS Scientific Sessions. 2016. Assumes terminated cases are paid in full because induction of anesthesia has already occurred upon termination.*

† Calculated as $119/minute x 9.3 minutes. Data from Winkle et al. Heart Rhythm. 2011 and Capone et al. PACE. 2015.

References

1. Mansour M, Karst E, Heist K, Packer D, Dalal N, Calkins H, Ruskin JN, Mahapatra S. Reduction in costs after AF ablation and impact of clinical events. Heart Rhythm Society (HRS) Scientific Sessions. 2016. [Abstract PO01-77]

2. Jauvert G, Grimard C, Lazarus A, Alonso C. Comparison of a radiofrequency powered flexible needle with a classic rigid Brockenbrough needle for transseptal punctures in terms of safety and efficacy. Heart Lung Circ. 2015. 173-8. doi: 10.1016/j.hlc.2014.07.073

3. Winkle RA, Mead RH, Engel G, Patrawala RA. The use of a radiofrequency needle improves the safety and efficacy of transseptal puncture for atrial fibrillation ablation. Heart Rhythm. 2011. 1411-5. doi: 10.1016/j.hrthm.2011.04.032

4. Hsu JC, Badhwar N, Gerstenfeld EP, Lee RJ, Mandyam MC, Dewland TA, Imburgia KE, Hoffmayer KS, Vedantham V, Lee BK, Tseng ZH, Scheinman MM, Olgin JE, Marcus GM. Randomized trial of conventional transseptal needle versus radiofrequency energy needle puncture for left atrial access (the TRAVERSE-LA study). J Am Heart Assoc. 2013. doi: 10.1161/JAHA.113.000428

5. Capone CA, Ceresnak SR, Nappo L, Gates GJ, Schechter CB, Pass RH. Three-catheter technique for ablation of left-sided accessory pathways in Wolff-Parkinson-White is less expensive and equally successful when compared to a five-catheter technique. Pacing Clin Electrophysiol. 2015. 1405-11. doi: 10.1111/pace.12742

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