

# **Comparison of *Monitored Anesthesia Care* versus *General Anesthesia* for Transcatheter Aortic Valve Replacement**



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# No Disclosures or Conflicts of Interest



# Objectives

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- Anesthesia consideration and selection criteria for MAC vs GETA for TAVI patients
- Discuss possible complications of TAVRs done under MAC
- Literature review of outcomes for TAVRs performed under MAC vs GETA



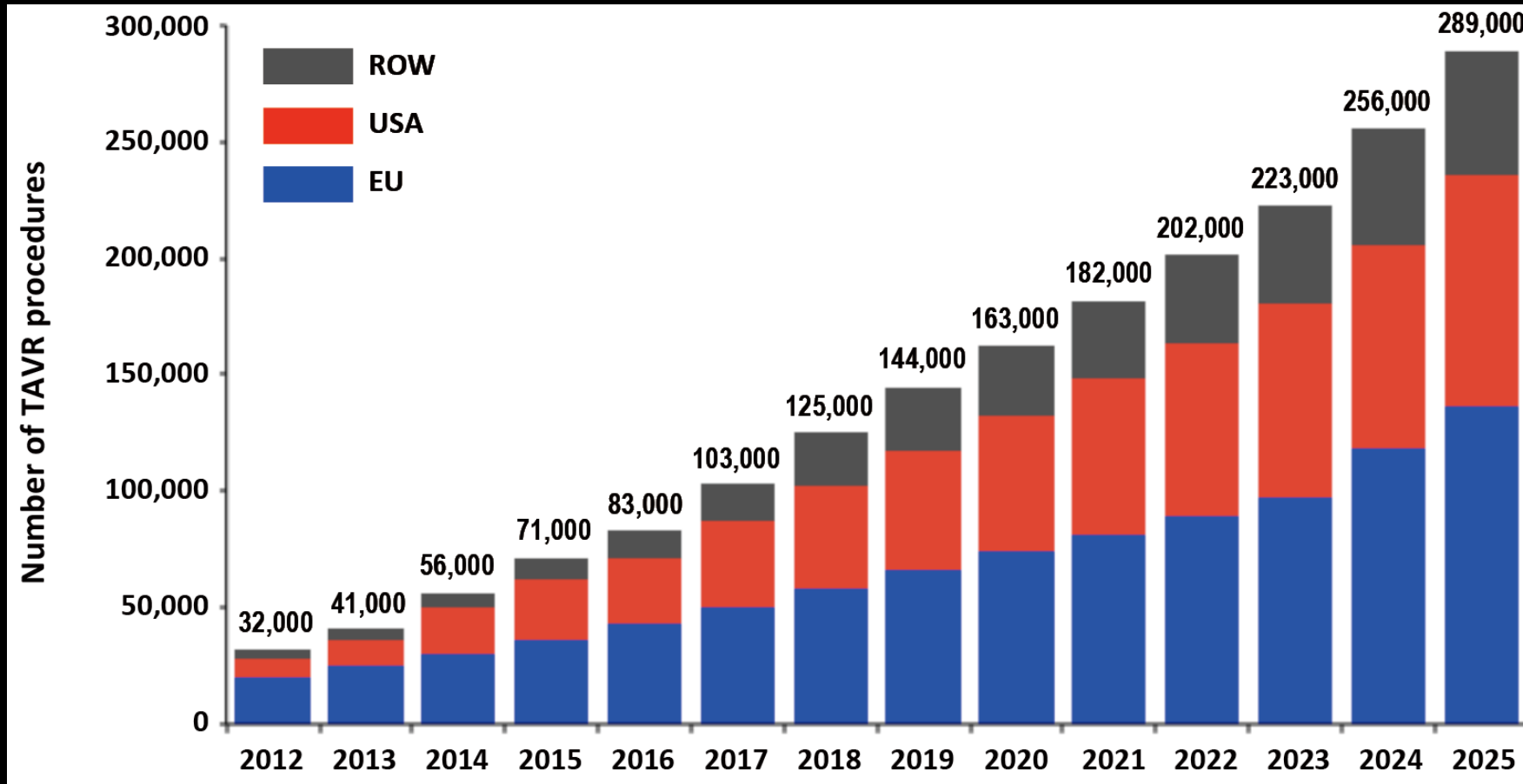
# Transcatheter Aortic Valve Replacement

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- Over 400,000 TAVRs have been performed worldwide
- First performed in Paris on April 16, 2002
- Was initially intended for non-surgical candidates; now FDA has approved intermediate risk candidates
- Studies are now being done to look at TAVR for low risk patients

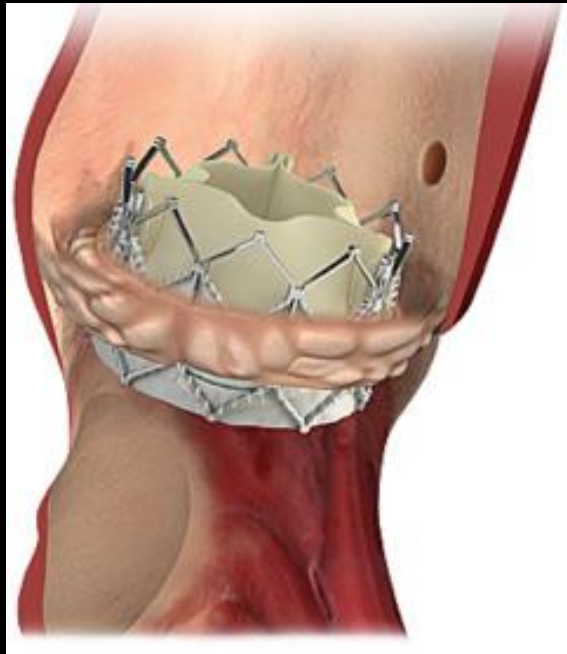


# TAVR Trends

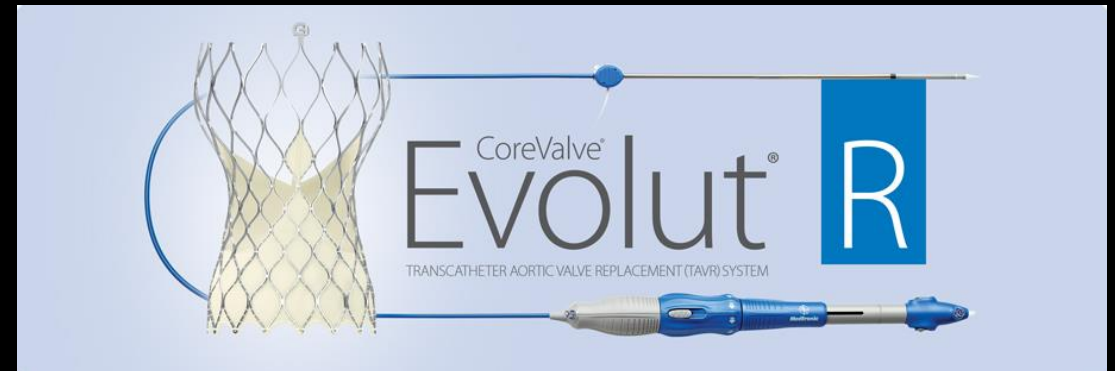


# Newest Generation Valves

## Edwards - Sapien 3



## Medtronic - CoreValve Evolut-R



# Anesthetic Considerations for TAVR

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- Oxygenation + Ventilation
- Monitoring – Arterial Line
- IV Access – Central Line?
- Echocardiography



# GETA vs MAC Criteria (Continued)

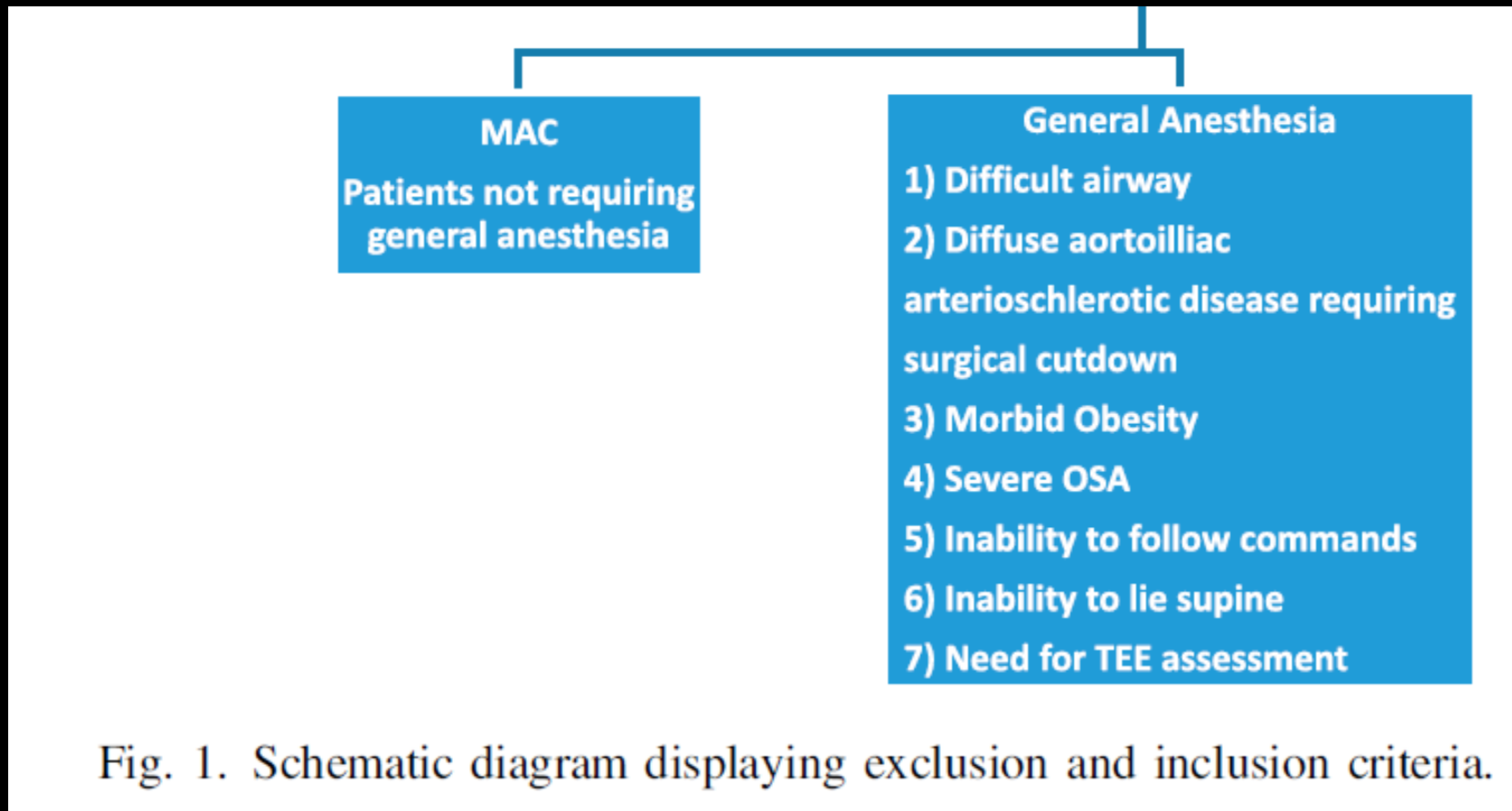


Fig. 1. Schematic diagram displaying exclusion and inclusion criteria.





# Advantages of General Anesthesia

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- Secured Airway with paralyzed patient
- Unlimited time for cardiologists to perform TAVR
- Allows for TEE Placement and Guidance
- Allows for quick conversion to surgical AVR, if necessary



# Disadvantages of General Anesthesia

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- Hemodynamic Fluctuations
- Increased risk of certain airway complications (prolonged intubation, pneumonia etc.)
- Prolongation of procedure time and ICU/length of stay



# Evolution of Monitored Anesthesia Care (MAC)

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- Operator improvement → Shorter duration procedures
- Technological advancements
  - Lower profile delivery systems
  - Retrievable/recapturable valves
  - Less paravalvular leak → less need for immediate echocardiography
- Minimalistic Approach



# Evolution of MAC (Continued)

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## GETA – Previous Steps

- Pre-induction A-line
- Induction/Intubation
- Central Line
- Foley Catheter

## MAC – Evolution

- No pre-induction A-line required
- No induction/intubation
- No central line (if no PPM)
- No Foley



# Advantages of MAC for TAVR

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- Less Hemodynamic Instability
- Avoidance of Intubation and Mechanical Ventilation
- Shorter operating room time and faster recovery times
- Ability to monitor for neurologic complications
- Less risk of postoperative delirium



# Disadvantages of MAC for TAVR

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- Unsecured Airway
  - Increased risk of aspiration
  - Hypoxemia, Hypercapnia → Pulmonary Hypertension
- Must be prepared for immediate conversion to GETA
  - Conversion rates range from 2%-17%
  - Usually secondary to cardiac instability and/or hypotension



**GETA vs MAC:  
Which is better?**

# MAC vs GETA Comparison - Outcomes

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**Local versus general anesthesia for transcatheter aortic valve implantation (TAVR) – systematic review and meta-analysis**

Georg M Fröhlich, et al. 2014





# Official Count

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MAC – **1**

GETA - 0



# MAC vs GETA Comparison - Outcomes

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## Clinical Outcomes and Safety of Transfemoral Aortic Valve Implantation Under General Versus Local Anesthesia

### Subanalysis of the French Aortic National

Atsushi Oguri, MD et al. August, 2014



# Oguri, A. et. al. – Analysis of FRANCE2

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- Data from 2326 patients in FRANCE2 Registry Reviewed (January, 2010 – October, 2011)
- GETA – 1377 patients, MAC – 949 patients
- Initially, GETA was used in 86% of cases vs 14% using MAC
- By the final month, GETA was used in 41% vs 59% using MAC



# Oguri, A. et. al. - Findings

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- TEE guidance needed more often in GETA vs MAC (76.3% v 16.9%,  $p < 0.001$ )
- Device success and 30 day mortality was similar between the groups
- **Incidence of post-procedure AI  $\geq$  mild was higher in MAC vs GETA (19.1% vs 15.0%,  $p = 0.015$ )**



# Official Count

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MAC – 1

GETA - **1**



# MAC vs GETA Comparison - Outcomes

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## General or Local Anesthesia for TAVI? A Systematic Review of the Literature and Meta-Analysis

Maas, EH et. al. - 2016



# Maas et. al. – Meta Analysis

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- 10 studies including 5919 patients from January 1, 2002 – February 15, 2015 were reviewed
- Outcome parameters were:
  - a. 30 day mortality
  - b. Length of hospital stay
  - c. Procedure duration
  - d. Use of adrenergic support
  - e. Safety Endpoints (stroke, AKI, AMI, etc.)



# Maas et. al. – Meta-Analysis

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- MAC – Shorter procedure time and hospital length of stay
- No statistically significant difference in other factors
- Statistically significant increase in paravalvular leak  $\geq$  mild  
(RR 1.31,  $p < 0.006$ )
- Statistically significant increase in need for implantation of PPM  
(RR 1.23,  $p = 0.02$ )





# Official Count

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MAC – **1.5**

GETA - **2**



# Comparison of MAC vs GETA for TAVR - Outcomes

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## Impact of Anesthesia Type on Outcomes of Transcatheter Aortic Valve Implantation (from the Multicenter ADVANCE Study)

Stephen J.D. Brecker, MD, et al. 2016



# Official Count

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MAC – 1.5

GETA – 2

**(No Change)**



# Comparison of MAC vs GETA for TAVR - Outcomes

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## Monitored Anesthesia Care Versus General Anesthesia: Experience With the Medtronic CoreValve

Christopher Palermo, DO, MPH et al. 2016



# Palermo et al – MAC vs GETA Study

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- N = 65 (GETA – 21, MAC – 44)
- No significant differences in:
  - a. 30 day mortality
  - b. ICU/Hospital Stay
  - c. Complication Rates
- Conversion Rate from MAC to GEN - 2.3% (1 patient out of 44)



# Official Count

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MAC – 1.5

GETA – 2

**(No change)**



# MAC vs GETA Comparison - Outcomes

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**Comparison of clinical outcomes with the utilization of monitored anesthesia care vs. general anesthesia in patients undergoing transcatheter aortic valve replacement**

Sarkis Kiramijyan, et al. 2016



# Study Endpoints

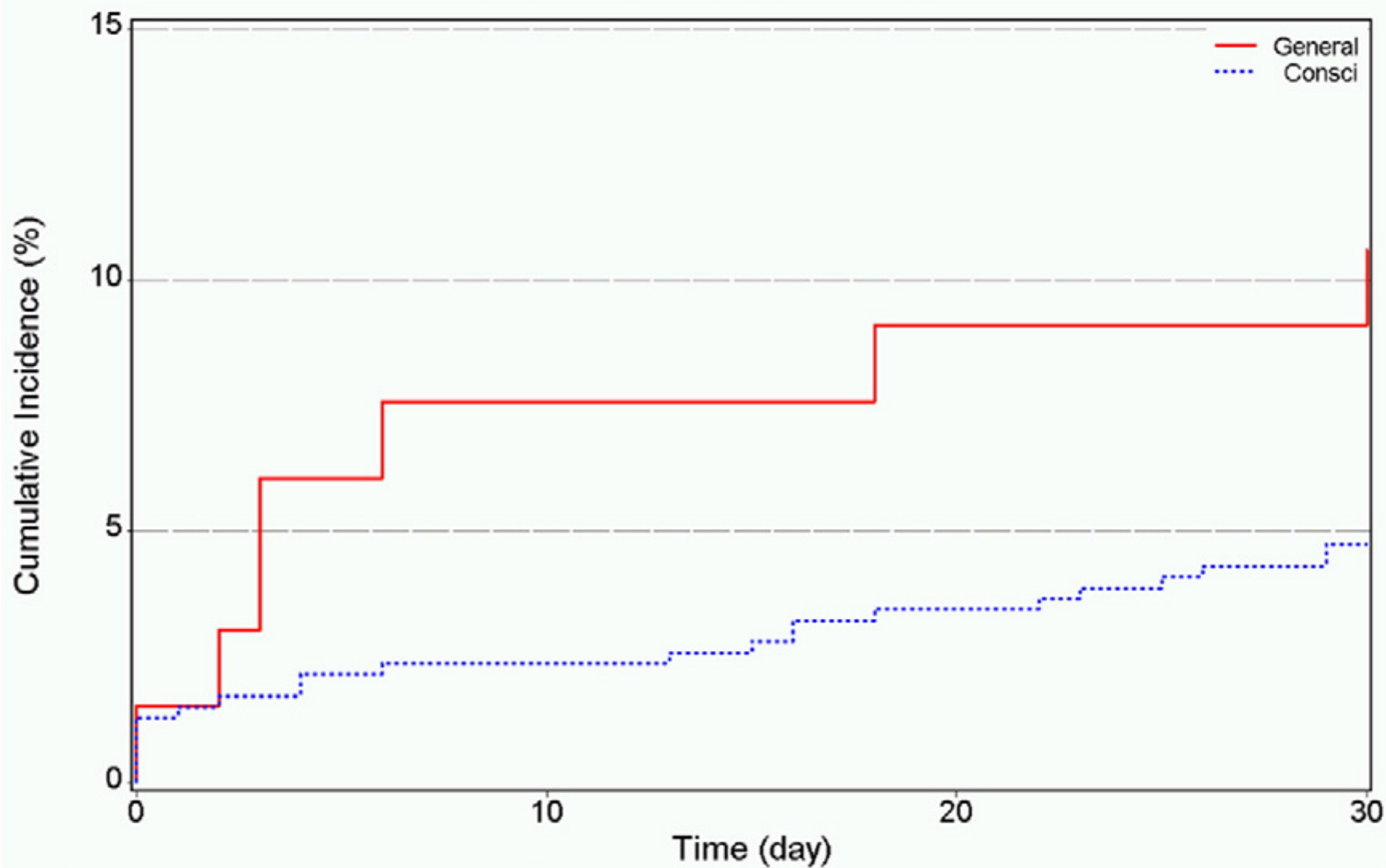
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- 30-day mortality
- 1 year mortality
- Rates and reasons for failure of MAC
- Post-procedural hospital and intensive care unit length-of-stays.



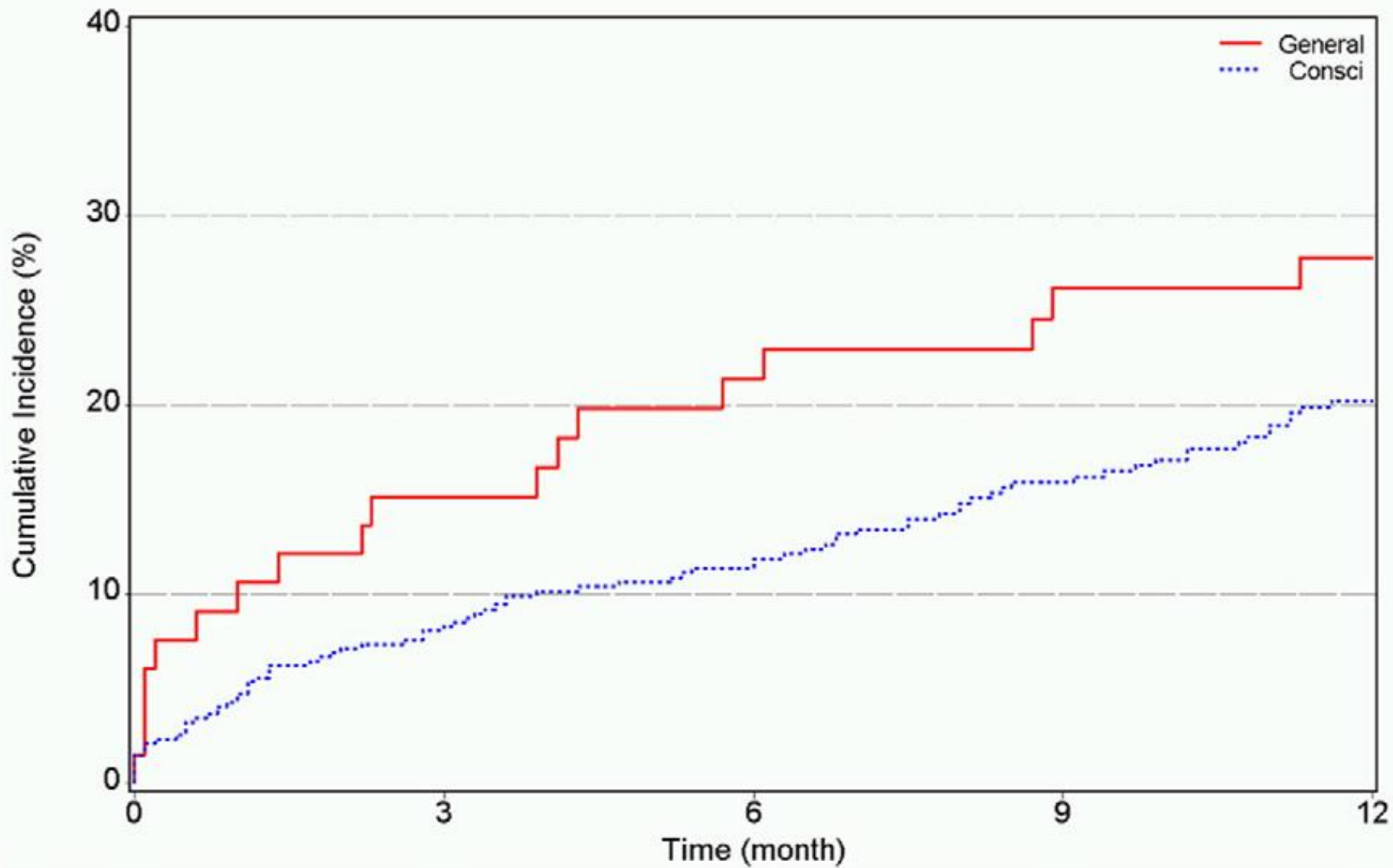


Kaplan-Meier Survival Estimate (Log-Rank p= 0.047)



| At Risk (n): | MAC: | 467 | 455 | 448 | 441 |
|--------------|------|-----|-----|-----|-----|
|              | GA:  | 66  | 61  | 60  | 60  |

Kaplan-Meier Survival Estimate (Log-Rank  $p=0.111$ )



|              |          |     |     |     |     |
|--------------|----------|-----|-----|-----|-----|
| At Risk (n): | MAC: 467 | 398 | 353 | 291 | 253 |
|              | GA: 66   | 55  | 50  | 46  | 44  |

# Official Count

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MAC – 2

GETA - 2



# Comparison of MAC vs GETA for TAVR - Outcomes

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## Outcome After General Anesthesia Versus Monitored Anesthesia Care in Transfemoral Transcatheter Aortic Valve Replacement – Analysis of OBSERVANT Trial

Paola D'Errigo, MStat, et al. - 2016



# D'Errigo et. al. – Observational Study

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- Multi-center, retrospective observation study with 1494 patients
- Findings: No difference between GETA and MAC for:
  - a. 30 day mortality
  - b. 3 year survival rate
  - c. Paravalvular leak
  - d. Permanent Pacemaker requirement



# Official Count

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MAC - 2

GETA – 2

**(No Change)**



# Summary of Studies

| Year | Author     | Study Type               | N    | Results | Conversion Rate |
|------|------------|--------------------------|------|---------|-----------------|
| 2014 | Froelich   | Review and Meta Analysis | 1542 |         | 6.3%            |
| 2014 | Oguri      | Analysis of FRANCE2      | 2326 |         | Not Mentioned   |
| 2016 | Maas       | Meta Anylysis            | 5919 |         | Not Mentioned   |
| 2016 | Brecker    | Analysis of ADVANCE      | 490  |         | 5.3%            |
| 2016 | Kiramijyan | Retrospective            | 533  |         | 12%             |
| 2016 | D'Errigo   | Observational            | 1494 |         | Not Mentioned   |
| 2016 | Palermo    | Retrospective            | 65   |         | 2.3%            |



# Conversion from MAC to GETA

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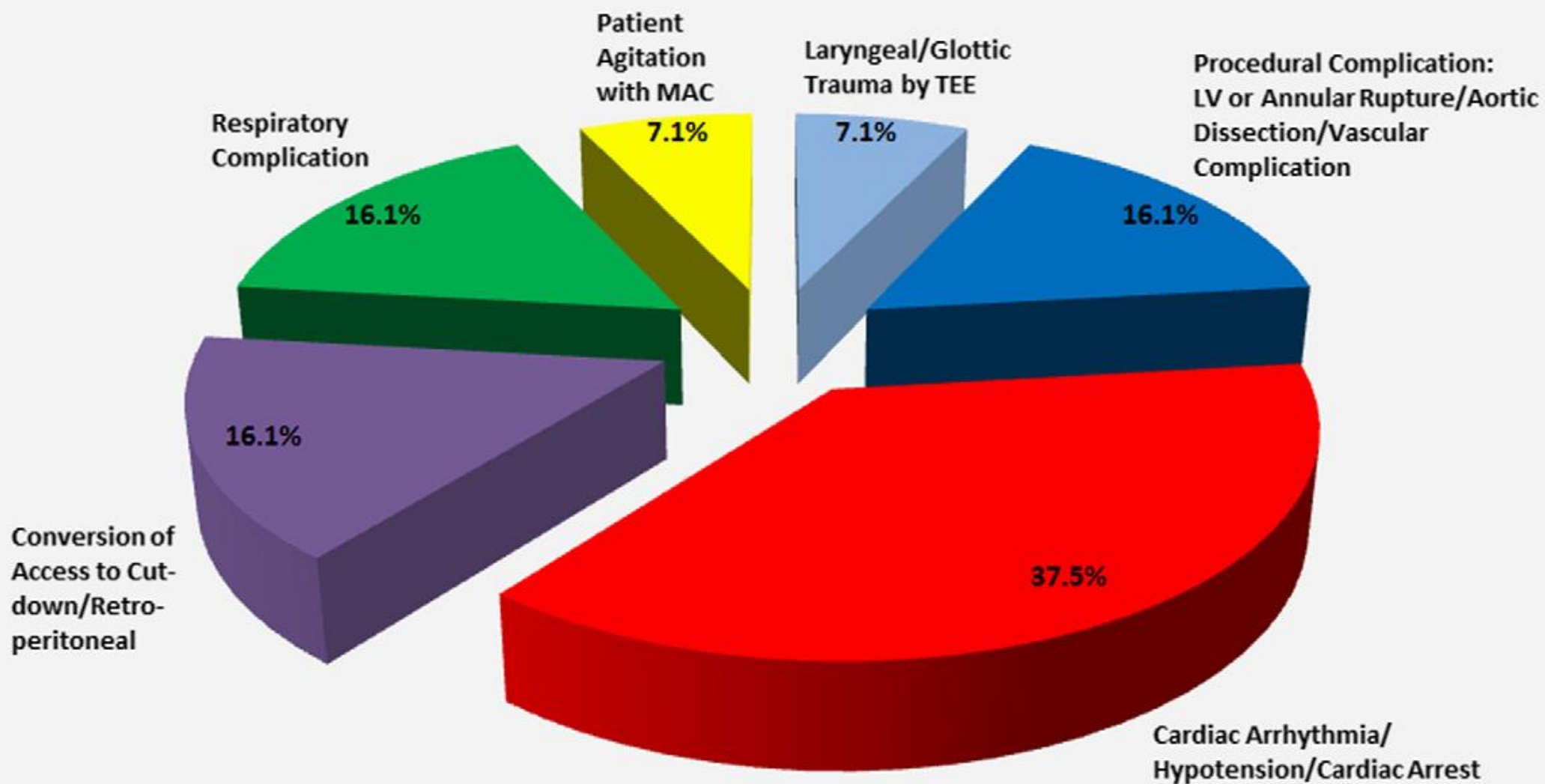
**Comparison of clinical outcomes with the utilization of monitored anesthesia care vs. general anesthesia in patients undergoing transcatheter aortic valve replacement**

Sarkis Kiramijyan, MD et. al. - 2016





Reasons for Failure of Monitored Anesthesia in 56 of 467 (12%) patients and conversion to General Anesthesia



# Keys to Success for TAVR with MAC

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- Patient Selection Criteria
- Candid discussion with patient regarding risks, benefits and alternatives of MAC vs GETA – Managing Expectations
- Coordination with Operator



# Conclusions

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- No randomized studies exist to compare GETA vs MAC for TAVR
- There is no difference in outcome between MAC vs GETA for TAVR
- MAC should be considered for select patients based on comorbidities and hospital practices
- A cardiac anesthesiologist must be present in case of emergent need for conversion to GETA





**THANK YOU FOR YOUR TIME!**



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