Surgical Ablation of Atrial Fibrillation

FDA

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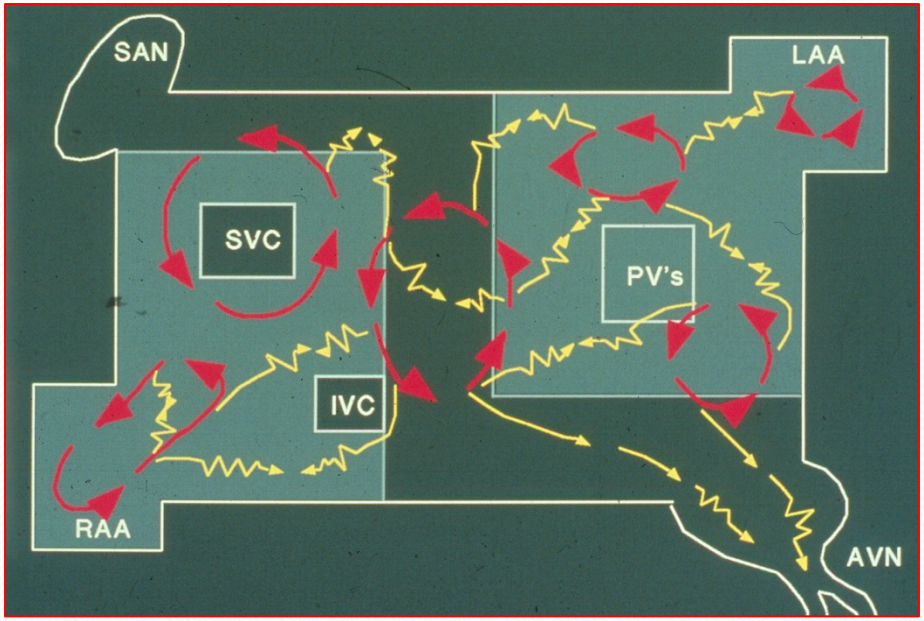
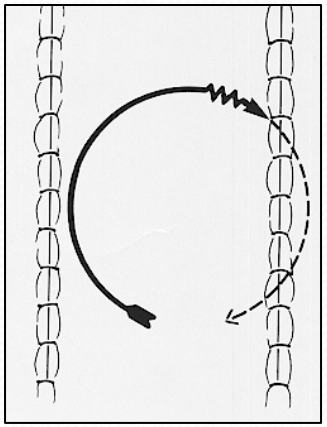
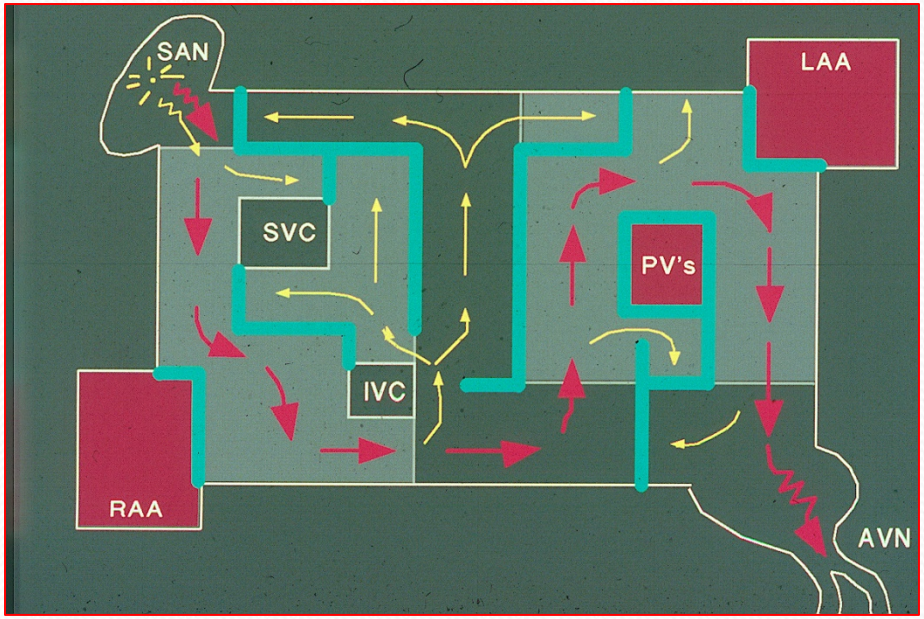
Cardiac surgery objectives

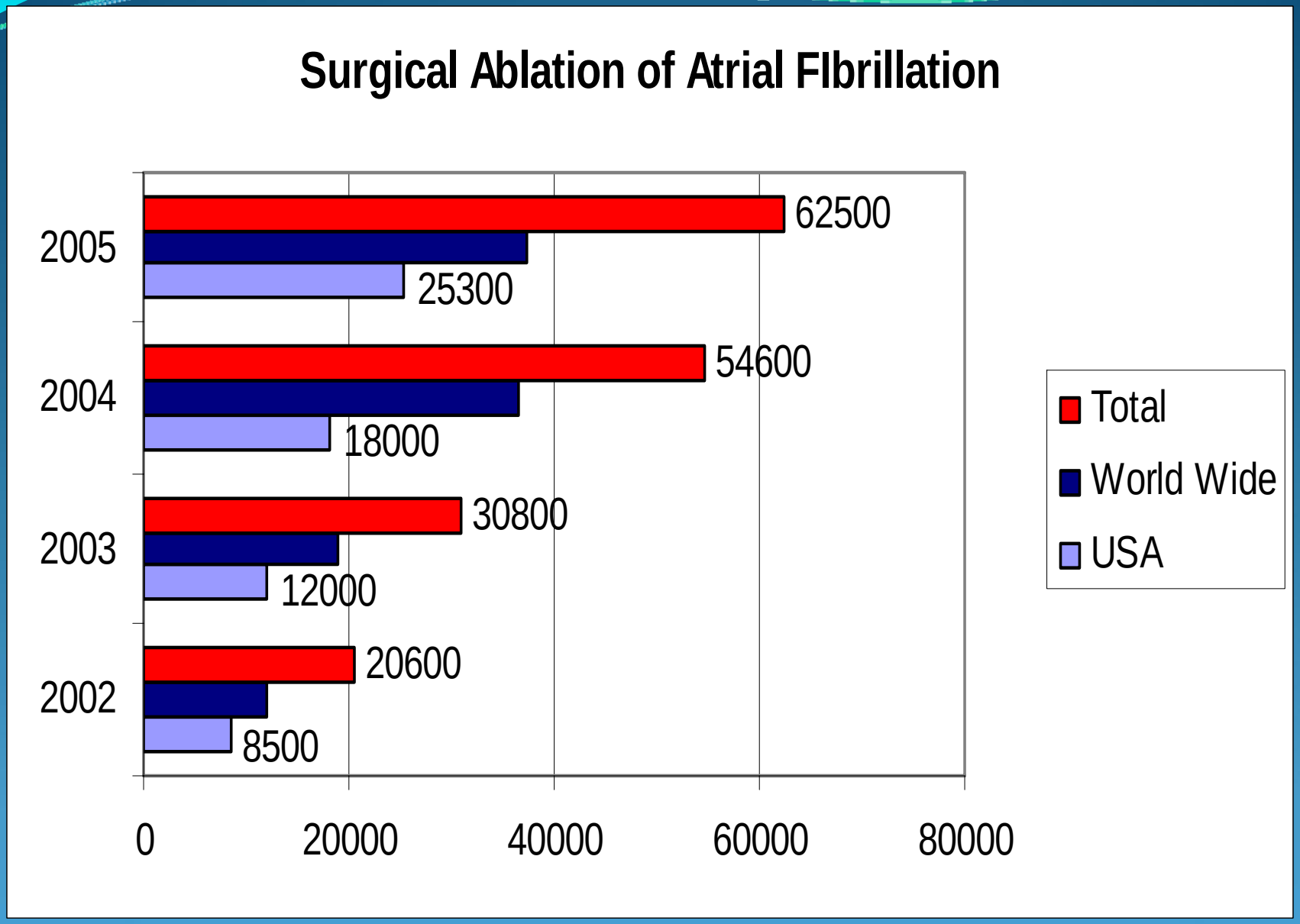
- Represent the value of the surgical treatment perspective
- Influence (particpate) in the process of setting the clinical benefit “bar” within reach to gain AF indication approvals
- Consider benchmarks for approval other than binary freedom from AF
  - Stroke reduction
  - AF burden
  - Medication

The Maze procedure








Surgical Ablation of Atrial FIbrillation
2005
2004
2003
2002
62500
25300
54600
18000
30800
12000
20600
8500
0
20000
40000
60000
80000
Total
World Wide
USA

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EDIT

How do we spell maze? A dialogue concerning definitions and goals

Niv Ad, MD

See related article on page 1433.

In this issue of the *Journal*, Ballaux and colleagues[1] from The Netherlands present their experience with more than 200 patients who underwent the cut-and-sew maze III procedure. The study was designed to assess the long-term

Value of Surgical Ablation

- Twenty years of experience
  - Animal experiments
  - Pre-Maze procedures (LA isolation, Atrial transection
  - Maze procedure (I-IV)
  - Modifications for the Maze
- Direct visualization provides safety and technical procedural advantages
  - Midsternotomy
  - Minimally invasive
- Effective ablation devices
  - Linear ablation
  - Transmural lesions
  - Conduction block
  - LA appendage

Value of Surgical Ablation

- HRS consensus statement states surgical ablation procedure may be considered in patients who have failed a catheter-based ablation procedure or choose to have the procedure
- Some patients who are not candidates for catheter-based ablation may be appropriate candidates and benefit from a surgical ablation procedure
  - LA thrombus
  - Very low yield
  - Issues with anticoagulation

Value of Surgical Ablation

- Results
  - Reports of excellent results
  - Significantly more effective for patients with
    - Persistent and longstanding AF
    - Enlarged left atrium
- Complication rate
  - Very low
  - Short hospital stay
    - Catheter ablation is not risk free!!!

What is the FDA view ?

- The role of surgery for AF
- The new HRS guidelines
- The new HRS classification
- Surgical Trials Methodology (Indication Devices)
  - RCT or others
  - Endpoints for Efficacy and Safety