**Table 2: Sutureless Clinical Study Publications**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Kocher, et al** | **Haverich, et al** | **Schlomicher, et al** | **Borger, et al** |
|  | **J Thorac Cardiovasc Surg 2013;145:110-6** | **J Thorac Cardiovasc Surg 2014;148:2854-61** | **J Thorac Cardiovasc Surg 2015;149:434-40.** | **Ann Thorac Surg 2015;99:17-25** |
| **Device used** | **EDWARDS INTUITY** | **EDWARDS INTUITY** | **EDWARDS INTUITY** | **EDWARDS INTUITY** |
|  |  |  |  |  |
| **Patient background** |  |  |  |  |
| # of patients | 146 | 287 | 60 | 46 |
| Mean age (y) | 75.5 ± 6.7 | 75.5 ± 6.7 | 75.5 ± 6.2 | 73.0 ± 5.3 |
| Male % | 47.3 | 50.7 | 61 | 58.6 |
| Mean log EuroSCORE % | 7.9 ± 6.5 | 8.4 ± 6.7 | 8.4 ± 4.2 | Not reported |
|  |  |  |  |  |
| **Procedure type** |  | Not reported |  |  |
| Isolated AVR n(%) | 86 (58.9) |  | 60 (100) | 46 (100) |
| Concomitant AVR n (%) | 60 (41.1) |  | n/a | n/a |
|  |  |  |  |  |
| **% MIS Use** |  | Not reported |  |  |
| Full sternotomy n(%) | 105 (69.9) |  | n/a | n/a |
| MIS approach n(%) | 44 (30.1) |  | 60 (100) | 46 (100) |
| Partial sternotomy n(%) | 43 (29.5) |  | 60 (100) | 46 (100) |
| Right anterior thoracotomy n(%) | 1 (0.7%) |  | n/a | n/a |
|  |  |  |  |  |
| **% MIS use in isolated AVRs** |  | Not reported |  |  |
| Full sternotomy n(%) | 44 (51.2%) |  | n/a | n/a |
| MIS approach n(%) | 42 (48.8%) |  | 60 (100) | 46 (100) |
| Partial sternotomy n(%) | 41 (47.7%) |  | 60 (100) | 46 (100) |
| Right anterior thoracotomy n(%) | 1 (1.1%) |  | n/a | n/a |
|  |  |  |  |  |
| **Technical Success rates** |  |  |  |  |
| (%) | 96.1 | 96 | 98.1 | 93.9 |
|  |  |  |  |  |
| **Procedural times** |  | Not reported |  |  |
| Overall (minutes) |  |  |  |  |
| XCT | Not reported |  | 26 ±7 | 41.3 ± 20.3 |
| CPB | Not reported |  | 56 ± 12 | 68.8 ± 29.0 |
| Isolated AVR (minutes) |  |  |  |  |
| XCT | 41.1 ± 10.6 |  | 26 ±7 | 41.3 ± 20.3 |
| CPB | 66.3 ± 18.7 |  | 56 ± 12 | 68.8 ± 29.0 |
| Concomitant AVR (minutes) |  |  |  |  |
| XCT | 60 ± 19 |  | n/a | n/a |
| CPB | 96 ± 30 |  | n/a | n/a |
|  |  |  |  |  |
| **Early Outcomes** |  |  |  |  |
| Mortality |  |  |  |  |
| ≤30 days, all cause n(%) | 3 (2.1) | 5 (1.7) | 1 (1.7) | 2 (4.3) |
| ≤30 days, valve related n(%) | 2 (1.4) | 0 (0) | 1 (1.7) | 0 (0) |
| Permanent pacemaker implantation n(%) | 7 (5) | 19 (6.9) | 1 (1.7) | 2 (4.3) |
| PVL |  |  |  |  |
| Major (≥2+) n(%) | 2 (1.4) | 2 (.7) | 1 (1.7) | 1 (2.9) |
| Stroke n(%) | Not reported | 8 (2.8) | Not reported | 2 (4.3) |
| Reoperation | 1 (0.7) | 22 (7.7) | 2 (3.3) | 1 (2.2) |
|  |  |  |  |  |
| **Mean pressure gradients (mmHg)** |  |  |  |  |
| Discharge | 9.8 ± 3.3 | 10.7 ± 4.2 | 11.4 ± 4.3 | Not reported |
| 3 months | 8.8 ± 3.0 | 9.0 ± 3.4 | Not reported | 8.5 ± 3.4 |
| 6 months | Not reported | Not reported | Not reported | Not reported |
| 12 months | 8.4 ± 3.4 | 9.0 ± 3.6 | 10.3± 3.8 | Not reported |
| 36 months | Not reported | 8.7 ± 4.1 (59) | Not reported | Not reported |
| 60 months | Not reported | Not reported | Not reported | Not reported |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Rubino, et al** | **Mazine, et al** | **Folliguet, et al** | **Gilmanov, et al** |
|  | **J Thorac Cardiovasc Surg 2014;148:865-71** | **Can J Cardiol 2015;31:63-8** | **Ann Thorac Surg 2012;93:1483-8** | **Ann Thorac Surg 2014;98:1585-92 ⁵** |
| **Device used** | **Perceval S** | **Perceval S** | **Perceval S** | **Perceval / Intuity/ 3F⁷** |
|  |  |  |  |  |
| **Patient background** |  |  |  |  |
| # of patients | 314 | 215 | 208 | 133 |
| Mean age (y) | 77.9 ± 5.0 | 78.9 ± 5.9 | 79 ± 5.3 | 75.3 |
| Male % | 39.8 | 46 | 32.2 | 55.6 |
| Mean log EuroSCORE % | 9.0 ± 7.6¹ | 7.2 ± 8.4¹ | 8.75 ± 5.3 | 5.83 (3.74 - 8.77)⁶ |
|  |  |  |  |  |
| **Procedure type** |  |  |  |  |
| Isolated AVR n(%) | 220 (70.1) | 102(47) | 160 (76.9) | 133(100) |
| Concomitant AVR n (%) | 94 (29.9) | 113 (53) | 48 (23.1) | n/a |
|  |  |  |  |  |
| **% MIS Use** |  |  |  |  |
| Full sternotomy n(%) | 174 (55.4) | 173 (80) | 163 (78.4) | n/a |
| MIS approach n(%) | 140 (44.6) | 42 (20) | 45 (21.6) | 133 (100) |
| Partial sternotomy n(%) | 131 (41.7) | 42 (20) | 45 (21.6) | n/a |
| Right anterior thoracotomy n(%) | 9 (2.9) | n/a | n/a | 133 (100) |
|  |  |  |  |  |
| **% MIS use in isolated AVRs** | Not reported |  | Not reported |  |
| Full sternotomy n(%) |  | Not reported |  | n/a |
| MIS approach n(%) |  | 42 (20) |  | 133 (100) |
| Partial sternotomy n(%) |  | 42 (20) |  | n/a |
| Right anterior thoracotomy n(%) |  | n/a |  | 133 (100) |
|  |  |  |  |  |
| **Technical Success rates** |  |  |  |  |
| (%) | 99.7 | 100 | 95.6 | Not reported |
|  |  |  |  |  |
| **Procedural times** |  |  |  |  |
| Overall (minutes) |  |  |  |  |
| XCT | 43 ± 20 | Not reported | 33.5 ± 13.8 | 56 (48 - 72.5)⁶ |
| CPB | 73 ± 28 | Not reported | 54.5 ± 24.2 | 90 (78 - 108.5)⁶ |
| Isolated AVR (minutes) |  |  |  |  |
| XCT | 39 ± 15 | 40.5±11.6 | 30.1 ± 12.2 | 56 (48–72.5)⁶ |
| CPB | 66 ± 23 | 56.6 ±16.6 | 50.3 ± 22.8 | 90 (78–108.5)⁶ |
| Concomitant AVR (minutes) |  |  |  |  |
| XCT | 52 ± 26 | 69.6 ± 28.8 | 44.2 ± 13.4 | n/a |
| CPB | 88 ± 32 | 88.7 ± 38.4 | 67.6 ± 23.9 | n/a |
|  |  |  |  |  |
| **Early Outcomes** |  |  |  |  |
| Mortality |  |  |  |  |
| ≤30 days, all cause n(%) | 10 (3.2) | 9 (4) | 5 (2.4) | 1 (0.8) |
| ≤30 days, valve related n(%) | 0 (0) | Not reported |  | Not reported |
| Permanent pacemaker implantation n(%) | 25 (8.0) | 37 (17) | 16 (7.7) | 6 (4.5) |
| PVL |  |  |  |  |
| Major (≥2+) n(%) | 40 (12.7)² | 0(0) | 18 (8.7) | Not reported |
| Stroke n(%) | 6 (1.9) | 7 (3) | 2 (1.0) | 2 (1.5) |
| Reoperation | 8 (2.5) | 10 (5) | 11 (5.2) | 9 (6.8) |
|  |  |  |  |  |
| **Mean pressure gradients (mmHg)** |  |  |  | Not reported |
| Discharge | 14 ± 6 | 13 ± 6 | 10.4 ± 4.3 |  |
| 3 months | Not reported | Not reported | 8.9 ± 3.2³ |  |
| 6 months | Not reported | Not reported |  |  |
| 12 months | Not reported | Not reported | 8.7 ± 3.7 ⁴ |  |
| 36 months | Not reported | Not reported |  |  |
| 60 months | Not reported | Not reported |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Biancari, et al** | **Shrestha, et al** | **Martens, et al** | **Englbarger, et al** |
|  | **Heart Vessels. 2015 Jan 9. [Epub ahead of print] ⁸** | **Eur J Cardiothorac Surg. 2015 Mar 6. [Epub ahead of print]** | **Eur J Cardiothorac Surg. 2011 Sep;40:749-55** | **J Thorac Cardiovasc Surg. 2014 Oct;148:1681-7** |
| **Device used** | **Perceval S** | **Perceval S** | **3F Enable** | **3F Enable** |
|  |  |  |  |  |
| **Patient background** |  |  |  |  |
| # of patients | 379 | 731 | 140 | 140 |
| Mean age (y) | 77.4 ± 5.4 | 78.5 ± 5.3 | 76 ± 6 | 76 ± 6 |
| Male % | 37.7 | 233 (31.9) | 38 | 38 |
| Mean log EuroSCORE % | 4.0 ± 3.9¹ | 10.9 ± 8.2 | Not reported | Not reported |
|  |  |  |  |  |
| **Procedure type** |  |  |  |  |
| Isolated AVR n(%) | 282 (74.4) | 498 (68.1) | 98 (70) | 98 (70) |
| Concomitant AVR n (%) | 97 (25.6) | 233 (31.2) | 42 (30) | 42 (30) |
|  |  |  |  |  |
| **% MIS Use** |  |  |  |  |
| Full sternotomy n(%) |  | 542 (74.1) | 112 (80) | 112 (80) |
| MIS approach n(%) | 205 (54) | 189 (25.9) | 28 (20) | 28 (20) |
| Partial sternotomy n(%) | 190 (50.1) | Not reported | 28 (20) | 28 (20) |
| Right anterior thoracotomy n(%) | 15 (3.9) | Not reported | n/a |  |
|  |  |  |  |  |
| **% MIS use in isolated AVRs** | Not reported | Not reported | Not reported | Not reported |
| Full sternotomy n(%) |  |  |  |  |
| MIS approach n(%) |  |  |  |  |
| Partial sternotomy n(%) |  |  |  |  |
| Right anterior thoracotomy n(%) |  |  |  |  |
|  |  |  |  |  |
| **Technical Success rates** |  |  |  |  |
| (%) | 80.5 | 95.6 | 85.6 | 85.6 |
|  |  |  |  |  |
| **Procedural times** |  |  |  |  |
| Overall (minutes) |  |  |  |  |
| XCT | 48 ± 22 | 38.8 ± 18.2 | 58.1 ± 25.1 | 58.1 ± 25.1 |
| CPB | 77 ± 29 | 63.0 ± 27.2 | 84.9 ± 34.2 | 84.9 ± 34.2 |
| Isolated AVR (minutes) |  |  |  |  |
| XCT | 42 ± 17 | 33.3 ± 11.7 | Not reported | Not reported |
| CPB | 71 ± 24 | 55.8 ±20.5 | Not reported | Not reported |
| Concomitant AVR (minutes) |  |  |  |  |
| XCT | 48 ± 22 | 51.0 ± 23.2 | Not reported | Not reported |
| CPB | 77 ± 29 | 78.9 ± 32.9 | Not reported | Not reported |
|  |  |  |  |  |
| **Early Outcomes** |  |  |  |  |
| Mortality |  |  |  |  |
| ≤30 days, all cause n(%) | 10 (2.6) | 3.4 | 5 (3.6) | 5 (3.6) |
| ≤30 days, valve related n(%) | Not reported | 1.9⁹ | 2 (1.4) | 2 (1.4) |
| Permanent pacemaker implantation n(%) | 37 (9.8) | 43 (6) | 10 (7) | 10 (.07) |
| PVL |  |  |  |  |
| Major (≥2+) n(%) | 1 (0.3) | 10 (1.4) | 3 (2.1) | 3 (2.1) |
| Stroke n(%) | 9 (2.4) | 12 (1.6) | 1 (0.7) | 1 (0.7) |
| Reoperation | 6 (4.2) | Not reported | Not reported | Not reported |
|  |  |  |  |  |
| **Mean pressure gradients (mmHg)** | Not reported |  |  |  |
| Discharge |  | 10.3 ± 4.4 | 10.24 ± 4.20 | 10.24 ± 4.20 |
| 3 months |  | 8.9 ± 4.3³ | 9.04 ± 3.56³ | 9.04 ± 3.56³ |
| 6 months |  | n/a | n/a |  |
| 12 months |  | 8.9 ± 4.7 | 8.62 ± 3.16 | 8.62 ± 3.16 |
| 36 months |  | 7.7 ± 2.8 | n/a | 8.7 ± 4.3 |
| 60 months |  | 8.8 ± 4.6 | n/a | 7.4 ± 3.4 |

|  |  |
| --- | --- |
| **¹ EuroSCORE II** | **⁶ Median and range** |
| **² Leak not clearly defined, includes mild and severe** | **⁷ Perceval 94%, Intuity 4%, Enable 3F 2%** |
| **³ 3-6 months follow-up** | **⁸ Only sutureless patients** |
| **⁴ 1-4 years follow-up** | **⁹ cardiac mortality** |
| **⁵ Propensity matched sutureless patients only** |  |