

# Lost to follow-up in a hip prosthesis register

## Experience of R.I.P.O.

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Patients undergoing hip arthroplasty are frequently lost to follow-up due to the generally good outcome of surgery. The lost to follow-up rate in local registers ranges from 5% (Berry et al. 1997) to 15% (Fender et al 2000).

In survival analysis it is commonly assumed that 'lost to follow-up patients' have the same outcome as those regularly checked. This hypothesis fits well with National Registers (Havelin 1999, Herberts and Malchau 2000, Lucht 2000), where the percentage of lost to follow-up is close to zero, but can be debated when applied to local registers. The hypothesis was for the first time proposed by Dorey (Dorey and Amstutz 1989), but other authors did not agree, as they proved that patients lost to follow-up had an inferior outcome than those that continue to be assessed (Murray et al. 1997), also in different orthopaedic scenarios such as shoulder surgery. (Wildner 1995).

At Rizzoli Orthopaedic Institute there is a register of all total hip arthroplasty (THA) operations that goes back to 1990 (Stea et al. 2001). The register was set up in 1997, and data was collected retrospectively from 1990. Since then the register has been kept up to date. The data collected for each operation include personal information, essential clinical data, antibiotic and antithromboembolic prophylaxis, main data on surgery and complications, stick-label-based description of implant components and fixation. Both primary and revision operations are registered.

In 11 years' practice, the percentage of lost to follow-up has been very high (51.1% patients or 50.3% hips). This is mainly due to two reasons:

- Rizzoli Institute is a national hospital, where patients come from all over Italy, often with complex diseases. The right column of Table 1 shows that more than 50% THA patients in the last ten years live outside the Emilia-Romagna region. Patients living in the Center and South of Italy are quite far from Rizzoli Institute (up to 1000 km), therefore it is easy for them to become 'lost to follow-up'.
- Many surgeons from our Institute are allowed to visit patients also in private hospitals, outside the Institute, mainly in the Center and South of Italy; at present time no report on this practice is forwarded to RIPO.

Among the aims of RIPO is monitoring the success of implants over time, verified by the elaboration of survival curves. Because of the high rate of patients lost to follow-up, the curves have until now been made assuming that patients who are lost to follow-up are neither more nor less likely to be at risk than patients who are still being followed (Dorey and Amstutz 1989). After a study carried out four years ago on a small sample of lost to follow-up patients, this hypothesis was strengthened, assuming that all the patients, who after at least one follow-up examination did not return to subsequent follow-up exams, continued to have non-revised prostheses.

Currently, the percentage of patients lost to follow-up is more than 50%, therefore, it is essential to verify the abovementioned hypothesis, because no implant register is at present implemented in Italy, and there is no previous experience to refer to with regard to the special geographic and social conditions of our country.

Table 1. Residence of patients treated by THA at Rizzoli, divided into patients regularly checked, and patients lost to follow-up

| Area of residence         | Patients followed-up | Patients lost to follow-up | Total        |
|---------------------------|----------------------|----------------------------|--------------|
| Emilia-Romagna            | 1644 (49.4%)         | 1103 (32.8%)               | 2747 (41.0%) |
| Other region of the North | 277 (8.3%)           | 238 (7.1%)                 | 515 (7.7%)   |
| Center                    | 568 (17.1%)          | 844 (25.1%)                | 1412 (21.1%) |
| South                     | 645 (19.4%)          | 863 (26.6%)                | 1508 (22.5%) |
| Islands                   | 193 (5.8%)           | 314 (9.3%)                 | 507 (7.6%)   |
| Foreign countries         | 3 (0.1%)             | 3 (0.1%)                   | 6 (0.1%)     |
| Total                     | 3330                 | 3365                       | 6695         |

Table 2. Result of telephone survey according to year of surgery

|                        | Year of surgery |      |      |      |      |      |      |      |      |      |       |
|------------------------|-----------------|------|------|------|------|------|------|------|------|------|-------|
|                        | 1990            | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | Total |
| Group A (72.2%)        |                 |      |      |      |      |      |      |      |      |      |       |
| Not revised prosthesis | 132             | 195  | 223  | 201  | 226  | 246  | 290  | 301  | 279  | 101  | 2194  |
| Dead *                 | 21              | 32   | 32   | 31   | 18   | 21   | 26   | 16   | 9    | 3    | 209   |
| Revised prosthesis     | 3               | 5    | 8    | 2    | 2    | 0    | 3    | 1    | 3    | 1    | 28    |
| Group C (27.8%)        |                 |      |      |      |      |      |      |      |      |      |       |
| Not found              | 118             | 130  | 139  | 108  | 100  | 112  | 85   | 68   | 50   | 24   | 934   |
| Total                  | 274             | 362  | 402  | 342  | 346  | 379  | 404  | 386  | 341  | 129  | 3365  |
| Group B                | 139             | 140  | 174  | 137  | 180  | 205  | 249  | 295  | 386  | 608  | 3330  |

\* Prosthesis in situ at time of death

Patients and methods

The number of patients, who had undergone primary total hip arthroplasty at Rizzoli from 1990 to 2000 in 8 out of the 9 surgical departments, was 5943, making a total of 6695 primary total hip replacements. These patients were usually followed-up 40 days, 6 months and 1 year after surgery, and then yearly.

We found that some patients were actually followed for the first two-three years after surgery, then they decided to give up. Other patients never started the follow-up program at Rizzoli Institute, as they decided to do so at another hospital.

In this study we considered all patients not attending clinical follow-up at our Institute during the last 18 months “lost to follow-up,” as six months delay on planned annual check-up was considered involuntary.

All these patients were contacted by phone in order to ascertain whether the prosthesis implanted at Rizzoli had been revised elsewhere; patients

who were impossible to reach were not included in the following analysis.

Results

The telephone survey gave the following results: 72% of patients were contacted in order to update the follow-up, whereas it was impossible to trace the remaining 28%, mainly due to relocation. After the telephone survey the population of our register was:

Group A: 2431 patients that were ‘lost to follow-up’, contacted by phone.

Group B: 3330 patients regularly checked at the Rizzoli Institute.

Group C: 934 patients definitively lost to follow-up, because it was not possible to reach them by phone.

The result of the phone calls is summarized in Table 2 and Figure 1.

Overall failure rate in Group A patients was 1.1%

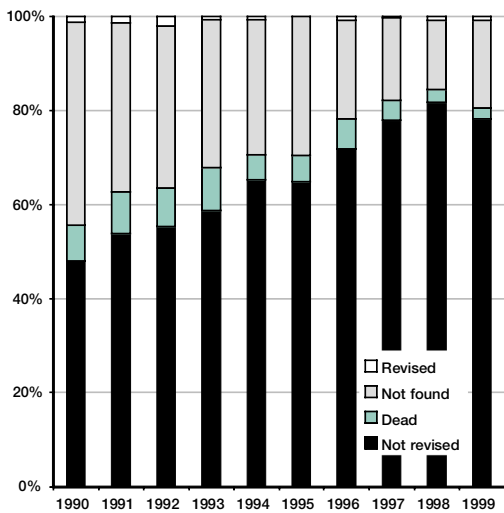


Figure 1 Distribution of telephone results according to year of surgery.

(28 revisions out of 2431 primary arthroplasties) in 11 years, lower than what we observed in Group B patients in the same period 7.3% (243 out of 3330); details are illustrated in Table 3.

The survival curve of Group A patients was then calculated. Definition of failure was revision for any cause of at least one prosthetic component. (Kaplan and Mayer 1958, Carr et al 1993) survival assessment was considered statistically reliable as long as 20% of the initial group stayed under observation. The confidence interval was placed at 95%.

Table 3 Percentage of failure (negative events/number of patients) in patients lost to follow-up (Group A), regularly checked patients (Group B) and total group (Group A+B+C) per year of surgery

| Year of surgery | Group A     | Group B       | Group A+B+C  |
|-----------------|-------------|---------------|--------------|
| 1990            | 3/156 = 1.9 | 37/139 = 26.6 | 40/413 = 9.7 |
| 1991            | 5/232 = 2.2 | 34/140 = 24.3 | 39/502 = 7.8 |
| 1992            | 8/262 = 3.1 | 25/174 = 14.4 | 33/575 = 5.7 |
| 1993            | 2/233 = 0.9 | 17/137 = 12.4 | 19/478 = 4.0 |
| 1994            | 2/243 = 0.8 | 24/180 = 13.3 | 26/523 = 5.0 |
| 1995            | 0/266 = 0   | 19/205 = 9.3  | 19/583 = 3.3 |
| 1996            | 3/318 = 0.9 | 20/249 = 8.0  | 23/652 = 3.5 |
| 1997            | 1/318 = 0.3 | 18/295 = 6.1  | 19/681 = 2.8 |
| 1998            | 3/291 = 1.0 | 13/386 = 3.4  | 16/727 = 2.2 |
| 1999            | 1/112 = 0.9 | 7/608 = 1.2   | 8/744 = 1.1  |
| 2000            | /           | 3/817 = 0.4   | 3/817 = 0.4  |

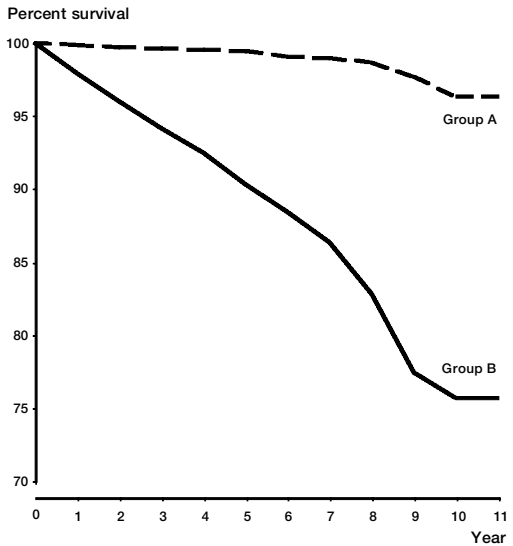


Figure 2. Survival curve and summary table of all primary total hip replacements performed at Rizzoli Institute. Group A patients were lost to follow-up, retraced by phone; group B patients were regularly checked at Rizzoli Institute.

Summary table

| Years follow-up | Group A<br>n at start: 2431<br>revisions: 28 |              |              | Group B<br>n at start: 3330<br>revisions: 217 |              |              | Diff.        |
|-----------------|----------------------------------------------|--------------|--------------|-----------------------------------------------|--------------|--------------|--------------|
|                 | % not revised                                | 95%CL        |              | % not revised                                 | 95%CL (A-B)  |              |              |
| 1               | 99.87                                        | 99.73        | 99.87        | 97.93                                         | 97.38        | 98.48        | 1.94         |
| 2               | 99.69                                        | 99.45        | 99.69        | 96                                            | 95.18        | 96.82        | 3.69         |
| 3               | 99.59                                        | 99.32        | 99.59        | 94.09                                         | 93.03        | 95.15        | 5.5          |
| 4               | 99.48                                        | 99.17        | 99.48        | 92.43                                         | 91.18        | 93.68        | 7.05         |
| 5               | 99.41                                        | 99.08        | 99.41        | 90.24                                         | 88.71        | 91.77        | 9.17         |
| 6               | <b>99.06</b>                                 | <b>98.59</b> | <b>99.06</b> | <b>88.41</b>                                  | <b>86.65</b> | <b>90.17</b> | <b>10.65</b> |
| 7               | 98.95                                        | 98.42        | 98.95        | 86.31                                         | 84.21        | 88.41        | 12.64        |
| 8               | 98.67                                        | 98.02        | 98.67        | 82.77                                         | 80.07        | 85.47        | 15.9         |
| 9               | 97.67                                        | 96.59        | 97.67        | 77.42                                         | 73.64        | 81.20        | 20.25        |
| 10              | 96.29                                        | 94.57        | 96.29        | 75.63                                         | 71.20        | 80.06        | 20.66        |
| 11              | 96.29                                        | 94.57        | 96.29        | 75.63                                         | 71.20        | 80.06        | 20.66        |

Bold type shows the limit of reliability of each curve

In Figure 2 survival curve of Group A patients is compared to the Group B curve. Statistical comparison by the Wilcoxon test and the Log-Rank test shows that curve A and curve B are statistically different ( $p=0.001$ )

At the end of the test patients of Group A were compared to patients of Group B, using any confounding factors (Table 4).

Table 4. Possible confounding factors in Group A and Group B (numbers refer to hips)

| Characteristics                         | Group A<br>hips = 2431 |       | Group B<br>hips = 3330 |       | Difference<br>p-value |
|-----------------------------------------|------------------------|-------|------------------------|-------|-----------------------|
| Age at surgery                          |                        |       | <0.05                  |       |                       |
| < 40                                    | 131                    | 5.4%  | 283                    | 8.5%  |                       |
| 41–69                                   | 1667                   | 68.6% | 2209                   | 66.3% |                       |
| > 70                                    | 633                    | 26.0% | 838                    | 25.2% |                       |
| Sex                                     |                        |       |                        |       | <0.05                 |
| Male                                    | 960                    | 39.5% | 1199                   | 36.0% |                       |
| Female                                  | 1471                   | 60.5% | 2131                   | 64.0% |                       |
| Etiology                                |                        |       |                        |       | <0.05                 |
| Osteoarthritis                          | 1541                   | 63.4% | 1993                   | 59.8% |                       |
| Rheumatoid arthritis                    | 62                     | 2.6%  | 91                     | 2.7%  |                       |
| Sequelae of CCD                         | 362                    | 14.9% | 610                    | 18.3% |                       |
| Femoral neck fracture                   | 139                    | 5.7%  | 210                    | 6.3%  |                       |
| Others                                  | 327                    | 13.4% | 426                    | 12.8% |                       |
| Prosthesis                              |                        |       |                        |       | <0.05                 |
| Cemented                                | 462                    | 19.0% | 376                    | 11.3% |                       |
| Uncemented                              | 1294                   | 53.2% | 2015                   | 60.5% |                       |
| Hybrid                                  | 666                    | 27.4% | 927                    | 27.8% |                       |
| uncem. cup, cem. stem                   |                        |       |                        |       |                       |
| cem. cup, uncem. stem                   | 9                      | 0.4%  | 12                     | 0.4%  |                       |
| CCD – congenital and childhood diseases |                        |       |                        |       |                       |

Significant differences were found between patients followed-up and those lost to follow-up in terms of age at surgery, aetiology and fixation of prosthesis. In Group A patients were older than in Group B, they were more often males and more often had cemented prostheses, depending on the department of surgery. The rate of complex diseases (sequelae of congenital dysplasia) in Group A was lower than in Group B.

## Discussion

Rizzoli Institute, situated in the region of Emilia-Romagna, in the north of Italy, is the only unspecialistic orthopaedic hospital in our country. Patients come not only from throughout the region, but from all the other regions of Italy. Moreover, the most complex diseases (sequelae of congenital hip dislocation, trauma, and revision surgery) are referred to our hospital. In fact, 915 patients underwent total hip replacement at Rizzoli Institute in 1999, of which 19.0% for revision; among primary surgery 17.6% was performed to treat congenital diseases. For comparison the mean percentage of revision surgery performed in all the other hospi-

tals of Emilia-Romagna is 11.8% and the percentage of patients treated for sequelae of congenital diseases is 12.5%.

Another peculiarity of Rizzoli Orthopaedic Institute is that nine wards operate independently, applying different treatments, and, to varying degrees, offering the patients the possibility to be followed-up, even in private healthcare structures. Until now it has not been possible to activate a system of recovery of observations carried out in structures other than our hospital.

For the above-mentioned reasons, the follow-up of patients treated by THA is not always easy and the percentage of lost to follow-ups has reached a very high level, preventing reliable survival curves to be drawn. The maximum percentage of lost to follow-ups must not exceed 20%.

Tracing patients was not always successful because often the telephone numbers of patients were not updated, as can be expected from patients who decide not to be followed-up at Rizzoli. The choice of direct contact by phone, as opposed to sending a questionnaire by post, was made because disappointing results of past experience.

The number of patients that were not traceable and were considered definitively lost to follow-up

(Group C) was higher as the number of years since surgery increased, with the inexplicable exception of those treated in 1999. A similar regular trend was observed for deaths. The number of negative events (revision surgery performed outside Rizzoli) has an irregular trend over the years, not correlated to the trend of negative events of patients followed-up at Rizzoli (Group B) Table 3.

The results showed that:

- Some characteristics of Group A patients are statistically different from those of Group B. According to what we had previously observed applying the Cox regression to our data (Toni, unpublished data), these characteristics are the ones that increase the risk of removal.
- Nevertheless, the cumulative percentage of revision in Group A is lower than in Group B (1.1 % vs 7.3%)

Therefore, attributing the same risk to patients lost to follow-up as to those regularly followed-up, inevitably leads to a falsely inferior result. On the other hand the hypothesis—up to now adopted to draw survival curves, of patients that do not return are well—is not correct.

Our next objective is to identify the relative risk of patients lost to follow-up, and apply it year by year to the population of the register, to verify the assumptions presented in this study by samples, every two years.

Thus we can conclude that it is important to obtain as much as up-to-date information on patients as possible, but this update is has not been crucial in our case in order to obtain valid survival curves.

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