Importance of Registry Data For Young Products

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The optimys prosthesis (Mathys Ltd Bettlach, Switzerland) belongs to the short stems and is used for total hip arthroplasty in patients with degenerative joint disease. Even though the first generation of short stems was already available in the 1980s, the safety of this type of prosthesis remains controversial. Typical clinical issues and early failure are related to implant migration resulting from limited primary and secondary stability1. The benefit of introducing new implants was shown to be critical2.

The present investigation focuses on safety aspects of the optimys stem documented in the Swiss Implant Registry (SIRIS). First implantation of the optimys stem was performed in 2010. In line with this, the availability of clinical data is limited.

It is hypothesized that even though the history of registry documentation is short, clinical data contribute to the safety evaluation of newly introduced implants.

The data set is comprised of 4688 optimys implantations performed between May 2012 and September 2016 with a mean follow-up of 614 days (range, 580 – 1596). The optimys stem was implanted in 45 Swiss hospitals by 143 surgeons.

Data analysis included the calculation of the revision rate and the respective confidence intervals (CI) for the optimys stem, which was compared to the revision rate of all other uncemented stems documented by SIRIS.

Kaplan Meier survival was calculated based on the revisions performed for the optimys stem.

The average age at surgery was 67 years (range, 14 – 98). In total, 51% of the patients were males. The main indication was osteoarthritis (90.0%), followed by osteonecrosis (4.5%), fracture (3.2%), developmental dysplasia (1.3%) and others (1.0%).

Revision surgery was performed in 80 cases leading to 1.00 revisions per 100 OCY (95% CI: 0.80 – 1.24). In 38 cases the femoral component was revised resulting in 0.48 revisions per 100 OCY (95% CI: 0.35 – 0.65).

The revision rate of femoral components for all other uncemented stems was 0.55 revisions per 100 OCY (95% CI: 0.51 – 0.61).

The average time from primary to revision surgery was 78 days (range, 31 – 575).

Revision surgery was performed for the following reasons: infection (n=21), luxation (n=19), loosening femoral component (n=15), periprosthetic fracture (n=13), loosening acetabular component (n=2), implant failure (n=1), acetabular protrusion (n=1), trochanter pathology (n=1), impingement (n=1), position/orientation of cup (n=1), other (n=9).

Evaluation of data from young registries such as SIRIS is helpful especially during the first years after market introduction to access the implant safety.

Furthermore, data supports the submission for implant ratings (e.g. ODEP). With increasing requirements regarding reimbursement, market introduction may be delayed in countries running well established national implant registries. Taking into account the learning curve for a new implant, the optimys stem shows good safety results in short-term perspective.

It can be concluded that there is crucial need for manufacturers to have access to individual registry reports also from young registries, especially for the safety evaluation of newly introduced implants.


Methods

Data from the Swiss Implant Registry(SIRIS) was assessed with respect to implant safety expressed as revisions per 100 observed component years (OCY).

Results

The optimys hip stem
left: standard version
right: laterialized version

Figure 1: optimys hip stem

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Kaplan Meier survival for the optimys stem.

Figure 2 shows the Kaplan Meier survival for the optimys stem.

Discussion

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Furthermore, data supports the submission for implant ratings (e.g. ODEP). With increasing requirements regarding reimbursement, market introduction may be delayed in countries running well established national implant registries. Taking into account the learning curve for a new implant, the optimys stem shows good safety results in short-term perspective.

Conclusion

It can be concluded that there is crucial need for manufacturers to have access to individual registry reports also from young registries, especially for the safety evaluation of newly introduced implants.

References