AOANJRR | Australian Orthopaedic Association National Joint Replacement Registry

How to Write a Registry Paper

October 2020

Introduction

As with all studies it is important to have a primary aim for the study. Registry based studies have the benefit of many recorded procedures but, as with all observational studies, there are many potential confounders that may make interpretation of the results complicated. Therefore, a clear primary aim helps to focus the study.

For example,

> *Example Text:*
>
> *The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) commenced data collection on 1 September 1999, achieving complete national implementation by mid 2002. Since then the AOANJRR has collected data on almost 100 percent of hip arthroplasty procedures performed in Australia. AOANJRR data are externally validated against patient-level data provided by all Australian state and territory health departments. A sequential, multilevel matching process is used to identify any missing data which is subsequently retrieved by contacting the relevant hospital. Each month in conjunction with internal validation and data quality checks all primary procedures are linked to any subsequent revision involving the same patient, same joint and same side. Data are also matched bi-annually with the Australian Government's National Death Index to obtain information on the date of death. Linking revision and death to the primary procedure enables revision rates to be determined.*

'Does the anterior approach to THA have a lower rate of revision than other approaches?' A secondary aim maybe something like 'Was there a lower rate of revision for dislocation or periprosthetic fracture'.

The introduction should briefly outline what is known about the subject and why your study is new and of relevance. Introductions do not need to be exhaustive but should summarise what is known and what you are trying to achieve from your investigation and whether your study adds something new to the literature. In the introduction Investigate if there have been other studies based on registry data. It would be prudent to examine the following registries (National UK, Swedish Hip or Knee, Norwegian, Nordic Arthroplasty Registry, New Zealand, Kaiser Permanente, and the Dutch) as all these registries have extensive publications on a variety of topics.

The last paragraph should clearly state the research question /aim.

Methods

The Registry has a few, standard paragraphs on Methods and Statistics that can be reproduced. Each study however has some specific inclusion criteria that form the basis of interrogating the registry data and these will need to be written specific for the research question(s).

Registry Background

As the paper you are writing is based on Registry data, you need to provide some background on the Registry.

For example:

> *Example Text:*
>
> The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) commenced data collection on 1 September 1999, achieving complete national implementation by mid 2002. Since then the AOANJRR has collected data on almost 100 percent of hip arthroplasty procedures performed in Australia. AOANJRR data are externally validated against patient-level data provided by all Australian state and territory health departments. A sequential, multilevel matching process is used to identify any missing data which is subsequently retrieved by contacting the relevant hospital. Each month in conjunction with internal validation and data quality checks all primary procedures are linked to any subsequent revision involving the same patient, same joint and same side. Data are also matched bi-annually with the Australian Government's National Death Index to obtain information on the date of death. Linking revision and death to the primary procedure enables revision rates to be determined.

The Study Population

This should be carefully defined at the start and any exclusions listed. The population could be all joints recorded if, for instance, the research question was an investigation of demographics or mortality. However, if the question is for a comparative analysis then generally we would suggest you restrict the population to all joints performed for a primary diagnosis of OA. This considers the known differences in outcomes by the primary diagnosis.

> *Example Text:*
>
> The study population included all primary THA performed for OA from September 1999 to end of the most recent year of validated data. Exclusions were (generally, we exclude large head MoM from THR data because of known higher rate of revision). Outcomes were compared between the two (or more) variables of interest. Reasons for revision and types of revision were examined. The Registry categories revision surgery as major or minor. A major revision involves the revision of either acetabular, femur or both (for hips), femoral or tibial or both, but not patella (for knees), and humeral or glenoid or both (for shoulders). Minor revisions are all other and are mainly head, liner and insert changes.

The above last three sentences are only needed if we are reporting on major and minor revision.

In order to account for possible confounders, we adjusted for age, sex (other possible factors include, femoral head, size, component fixation, surgical volume, patella resurfacing etc.).

Since 2015, we also have data on BMI and ASA for all joints and surgical approach for THA so these maybe examined in a sub-analysis, but they will reduce the numbers available for the analysis of the primary aim.

It is also possible to stratify as well when this seems more clinically practical.

> i.e. <65 years or over 65 years of age particularly for TKR as there are large differences in revision rates, stratification for femoral head size with THR studies into three widely used groups, <32mm, 32mm, >32mm.

If the analysis is on data that we have recorded from a later time period, then it may be sensible to restrict the analysis to that time period. For example, computer navigation was introduced for THA in early 2000's but there were minimal numbers recorded up to 2008. Journal editors often comment on the secular (time related changes) that may be confounders if all the data from September 1999 is included in the analysis. Therefore, a study comparing navigated to non-navigated THR would be best restricted to a time period from 2009 onwards.

If the exposure of interest is used with multiple prostheses or prosthesis combinations, we would also suggest a prosthesis specific analysis i.e. *We also performed a prosthesis specific analysis to account for known prosthesis related outcome variation*. We would generally choose prostheses with large numbers and a certain minimum follow-up which the Registry can assess based on the available data. (The Registry working group will often do a preliminary check to determine if there are enough procedures to perform the specific request). This type of analysis helps consider the different rates of revision for different prostheses

> Example: 2020 Annual Report Total Hip Chapter comparing the rate of revision between non-XLPE vs XLPE for THA. A prosthesis specific analysis was performed to investigate the outcome when both types of polyethylene are used in the same acetabular shells.

Prosthesis Specific Analysis

> *Example Text:*
>
> Further analysis has been undertaken for specific acetabular prostheses that have both XLPE and non XLPE bearing options and at least 500 procedures in each group. Six prostheses fulfil these criteria. Five have a reduced rate of revision when XLPE is used and for one prosthesis there is no difference.

An analysis based on surgeon or hospital volume can also be considered but this does require large numbers for comparison between surgical groups and we can only include known surgeons (surgeon matched to surgeon number).

Challenging areas

Furthermore, many concepts such as surgeon volume are difficult to define, as they involve many incorporate factors such as current volume (e.g. last 12 months), past volume (e.g. the 3 years before that), lifetime volume (e.g. since starting practice), non-linear associations (e.g. there may be a strong association with volume up to a certain point, then no association), and volume (total cases) versus rate (e.g. cases per year).

Perhaps the main area of difficulty in writing Registry papers is in determining causation. Causal conclusions may be used when dealing with Registry (observational data) but such conclusions must be clearly explained and justified, and relevant caveats provided. Often, analyses cannot

conclude casual associations (e.g. if important confounders remain unmeasured); this should be reflected in the language used in the manuscript.

Authors *should keep in mind that the outcome used in Registry papers may differ from the desired* outcome. For example, revision for infection, dislocation or periprosthetic fracture is not the same as the overall incidence of infection, dislocation or periprosthetic fracture (i.e. many of these outcomes are not treated with revision. This should be reflected in the language used (e.g. the use of heads sizes 32mm or larger was **associated** with a reduction in the risk of revision for dislocation compared to head sizes less than 32mm)).

Statistics

The Registry uses standard statistical methods to analyse data unless otherwise stated. For example:

> *Example Text:*
>
> Kaplan-Meier estimates of survivorship were used to report the time to second revision, with censoring at the time of death and closure of the dataset at the end of December 2018. The unadjusted cumulative percent revision (CPR), with 95% confidence intervals (CI), were calculated using unadjusted point wise Greenwood estimates. Age and gender adjusted hazard ratios (HR) were calculated from Cox proportional hazard models to compare the rate of second revision between groups. The assumption of proportional hazards was checked analytically for each model. If the interaction between the predictor and the log of time was statistically significant in the standard Cox model, then a time varying model was estimated. Time points were selected based on the greatest change in hazard, weighted by a function of events. Time points were iteratively chosen until the assumption of proportionality was met and HRs were calculated for each selected time-period. For the current study, if no time-period was specified, the HR was calculated over the entire follow-up period. All tests were two-tailed at 5% levels of significance. Statistical analysis was performed using SAS software version 9.4 (SAS Institute Inc., Cary, North Carolina).

Funding Statement

The Australian Government funds the AOANJRR through the Department of Health. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

This is valid for all Registry staff but may not be for other authors and it is the responsibility of first author to check.

Ethics Statement

The AOANJRR is approved by the Commonwealth of Australia as a federal quality assurance activity under section 124X of the Health Insurance Act, 1973. All AOANJRR studies are conducted in accordance with ethical principles of research (the Helsinki Declaration II).

Results

Demographic information should be presented first. In some journals (i.e. CORR) this is required in the methods section so check the journal requirements.

For example, the results section can start with a paragraph describing the study population and a comparator group if appropriate. 'The Registry recorded x number of procedures with n done with this and m with the comparator. 'Then describe the demographics and we would give a table of age, mean (SD), gender (numbers and %) and length of follow-up, median (IQ range) along with any other information pertinent to the study groups. This would usually be Table 1 (See example Table 1 for demographics which can be modified depending on needs and journal requirements).

Table 1 Summary of Primary Total Conventional Hip Replacement by Liner Use (Study population Primary Diagnosis Fractured NOF from 2013 onwards)

Variable		Dual Mobility Liner	Standard Liner	TOTAL
Follow Up Years				
	Mean ± SD	1.9 ± 1.5	2.4 ± 1.7	2.3 ± 1.7
	Median (IQR)	1.5 (0.6, 2.8)	2.1 (0.9, 3.7)	2 (0.9, 3.6)
	Minimum	0	0	0
	Maximum	6	6	6
Age				
	Mean ± SD	75 ± 10.7	73.5 ± 10.7	73.7 ± 10.7
	Median (IQR)	76 (68, 83)	74 (67, 81)	74 (67, 82)
Gender				
	Male	479 (29.7%)	2,696 (28.4%)	3,175 (28.6%)
	Female	1,133 (70.3%)	6,800 (71.6%)	7,933 (71.4%)
ASA[1]				
	1	42 (2.7%)	465 (5.2%)	507 (4.9%)
	2	511 (32.8%)	3,507 (39.5%)	4,018 (38.5%)
	3	832 (53.5%)	4,234 (47.7%)	5,066 (48.5%)
	4	170 (10.9%)	674 (7.6%)	844 (8.1%)
	5	1 (0.1%)	4 (0%)	5 (0%)
BMI[2]				
	Underweight (<18.50)	59 (6.5%)	226 (5.4%)	285 (5.6%)
	Normal (18.50-24.99)	424 (47%)	1,827 (43.5%)	2,251 (44.1%)
	Pre-Obese (25.00-29.99)	277 (30.7%)	1,421 (33.8%)	1,698 (33.3%)
	Obese Class 1 (30.00-34.99)	93 (10.3%)	502 (12%)	595 (11.7%)
	Obese Class 2 (35.00-39.99)	35 (3.9%)	165 (3.9%)	200 (3.9%)
	Obese Class 3 (≥40.00)	15 (1.7%)	57 (1.4%)	72 (1.4%)
Femoral Cement				
	Cementless	272 (16.9%)	2,837 (29.9%)	3,109 (28%)
	Cemented	1,340 (83.1%)	6,659 (70.1%)	7,999 (72%)
Bearing Surface[3]				
	Ceramic/Ceramic		435 (4.6%)	435 (3.9%)
	Ceramic/Non XLPE	92 (5.7%)	22 (0.2%)	114 (1%)
	Ceramic/XLPE	86 (5.3%)	1,703 (18%)	1,789 (16.1%)
	Metal/Metal		3 (0%)	3 (0%)
	Metal/Non XLPE	154 (9.6%)	413 (4.4%)	567 (5.1%)
	Metal/XLPE	1,256 (77.9%)	6,507 (68.6%)	7,763 (70%)
	Ceramicised Metal/Non XLPE	1 (0.1%)		1 (0%)
	Ceramicised Metal/XLPE	23 (1.4%)	400 (4.2%)	423 (3.8%)
Approach[4]				
	Anterior	76 (5.8%)	920 (14.5%)	996 (13%)
	Lateral	364 (27.9%)	1,908 (30.2%)	2,272 (29.8%)
	Posterior	867 (66.3%)	3,500 (55.3%)	4,367 (57.2%)
Hospital Setting				
	Private Hospital	673 (41.7%)	3,099 (32.6%)	3,772 (34%)
	Public Hospital	939 (58.3%)	6,397 (67.4%)	7,336 (66%)
TOTAL		1,612	9,496	11,108

Note: Abbreviations: SD - standard deviation, IQR - interquartile range, ASA - American Society of Anesthesiologists, BMI - Body Mass Index (kg/m^2)

[1]Excludes 668 procedures with unknown ASA

[2]Excludes 6,007 procedures with unknown BMI

[3]Excludes 13 procedures with unknown Bearing Surface

[4]Excludes 3,473 procedures with unknown Approach

Then describe the findings of the study. As the registry outcomes are time to first revision it is best to state this first. Then describe the reasons for revision and a sentence if there was a difference in the types of revisions between two groups. If you are comparing a specific reason for revision (i.e. dislocation after THR) this will require further sentence on CPR and HR.

Example of appropriate text to describe registry data:

> *Example Text:*
>
> THR performed with XLPE has a lower rate of revision compared to non XLPE after 6 months. (The cumulative percent revision at 19 years was 8.2% for XLPE and 14.9% for non XLPE (10 years + HR = 2.9 (95% CI 2.6,3.2),p<0.001) (Fig 1).
>
> Prostheses with XLPE had a lower rate of revision for dislocation, loosening, and lysis. The cumulative percent revision for dislocation at 17 years was…..*etc*.
>
> *Note: when describing CPR for a specific diagnosis the follow up time is usually shorter than for overall rate of revision because there are reduced numbers for analysis and the registry applies cut off rules for appropriate numbers*

Prosthesis specific analysis is often recommended as part of the study to take into account known differences in prostheses outcomes. This can be reported here.

For example:

> *Example Text:*
>
> The Reflection shell (Smith & Nephew) has a higher rate of revision with the use of non-XLPE compared to XLPE. The cumulative percent revision at 17 years was 20.6%% for non XLPE and 6.0% for XLPE (12 years + HR =4.7 (95% CI 3.2,7.0), p<0.001) (Fig 2).
>
> *Note: decimal points vary by journal and author instructions will need to be checked. Generally, one decimal point is required for CPR and hazard ratios*

Figure 1: Comparison of XLPE and non XLPE for THR overall

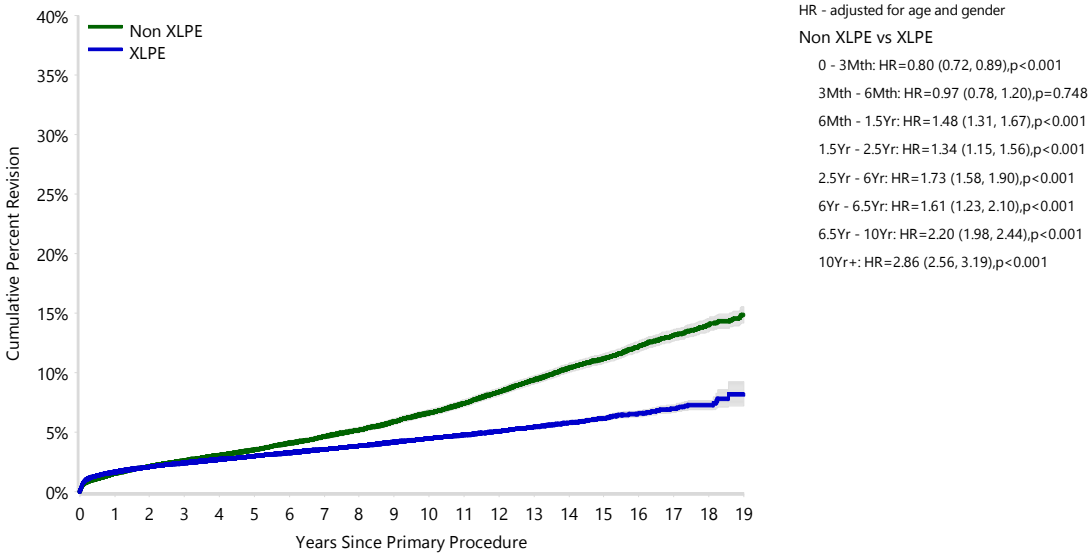
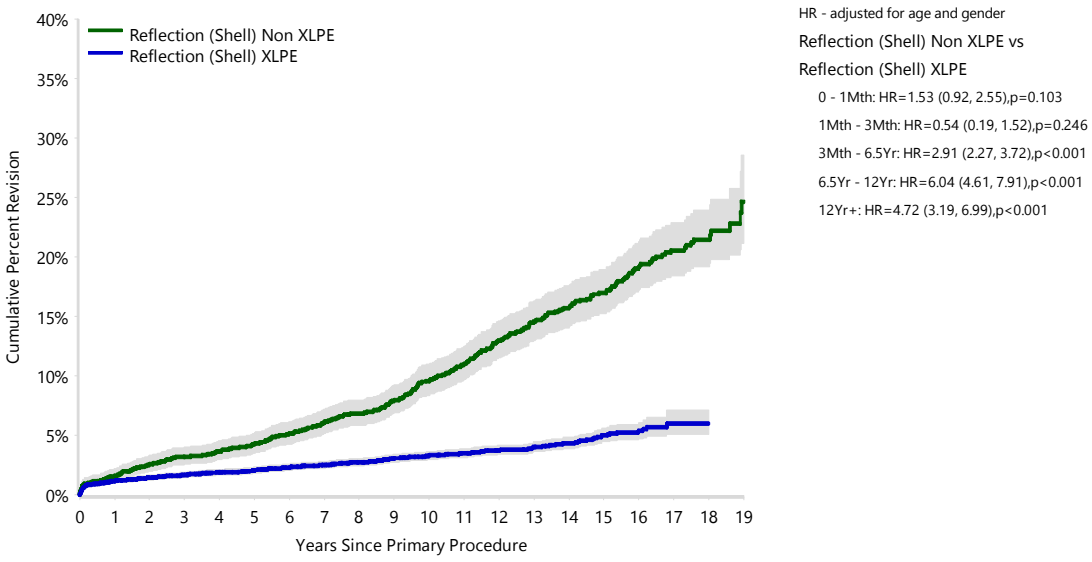


Figure: 2 Comparison of XLPE and non XLPE for THR prosthesis specific: Reflection shell



Discussion

In general, the Discussion should cover the following areas:

1. Summarise the main findings, reject or accept your hypothesis.
2. What are the clinical implications of these findings – what do they mean and why should we care? Include an explanation of the findings, if necessary.
3. How do these findings fit with what is known? (compare and contrast with previous studies, particularly RCTs and other registry studies, and explain any differences).
4. Strengths (e.g. 'A major strength of this study was the use of data from an entire national population', mention methods used to reduce bias).
5. Limitations.
    a. Consider variation in length of follow up which could have affected results. Could state that "we do not believe that trends in surgical technique, peri-operative care or rehabilitation would have likely affected the results".
    b. Consider relevant unknown outcomes: X-Rays, patient activity, patient-reported outcomes, blood tests etc.
    c. Confounding (known and unknown) is an issue with observational data. Comment on how this has been minimized or how likely it is to have affected results.
    d. May need to note again that outcomes are for revision procedures only (e.g. revision for infection does not measure all infections).
    e. Specifically mention how (if) the limitations affected the results.

What not to do

Do not introduce discussion around topics that are outside of the data in the results provided by the Registry. Do not introduce new results in the discussion or repeat large sections of results verbatim.

Conclusion

This just needs to be a brief paragraph summarising the main finding of the study, its clinical relevance and specific avenues for further research if suggested by your findings. Avoid bland statements like "further research is needed in this area".

Acknowledgements

We thank the AOA National Joint Replacement Registry and the hospitals, orthopaedic surgeons, and patients whose data made this work possible.

References

Make sure you reference the article correctly depending on journal requirements. Usually in order of reference but can be alphabetical (e.g. CORR). Using referencing software such as Endnote or RefWorks will make the task of formatting references less time consuming. Please include other Registry references, and as these and other reports are usually accessed via a website, the date accessed should be included as well.

> i.e. Concerns about Metal-on-Metal Hip Implants. 2015; https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241604.htm. Accessed July 2017.

The AOANJRR should be referenced like this and put the date of access:

> i.e. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Hip, knee and shoulder arthroplasty: 2019 Annual Report. Adelaide: Australian Orthopaedic Association;2019.Available from: https://aoanjrr.sahmri.com/annual-reports-2019; accessed 24 August 2020.