Patient Outcomes of Hip Resurfacing Compared to Total Hip Arthroplasty

A Systematic Review

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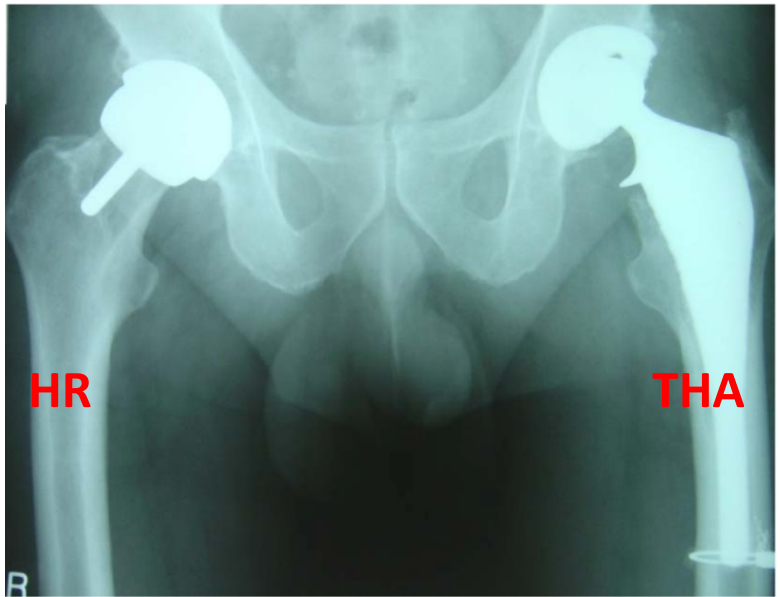
Introduction and Objectives

HR vs. THA

- Hip resurfacing (HR) was developed as a surgical alternative to total hip arthroplasty (THA)

- **HR**:
  - Head of the femur not completely removed
  - New metal head that fits a metal acetabular component
  - Also referred to as metal-on-metal (MOM) implant

- **THA**:
  - Head of femur and acetabulum ("socket") are removed and replaced
  - Also referred to as a total hip replacement



Sandiford *et al. Journal of Orthopaedic Surgery and Research* 2010, **5**:8 doi:10.1186/1749-799X-5-8

Issue

- Safety of HR is controversial
  - Concerns over adverse events and early device failure
- Limited long-term follow-up regarding overall safety and estimated revision rates for HR

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Hip resurfacing failures in women called too high

Hip resurfacing not recommended in women, British surgeons advise

CBC News Posted: Oct 3, 2012 10:57 AM ET | Last Updated: Oct 3, 2012 10:56 AM ET

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An alternative operation to hip replacements has a high failure rate, a British study suggests.

Hip resurfacing is similar to total hip replacements except the rounded top section of the thigh bone, called the femoral head, is replaced with a metal cap instead of removing it completely.

Hip resurfacing uses metal-on-metal bearings and is often used as an alternative to hip replacements in younger, active patients.

Regulators worldwide are looking at the failure rates of various types of hip implants. (Charles Rex Arbogast/Associated Press)

Authorities in Canada, the U.S. and the UK have issued warnings about full metal-on-metal hip implants, saying they may be more likely to fail and can cause tissue damage around the joint compared with the traditional metal-and-plastic type of implants.

External Links

- Metal-on-metal hip implant safety, Health Canada

(Note:CBC does not endorse and is not responsible for the content of external links.)

THE GLOBE AND MAIL

March 2, 2013

The nightmare of Margaret Wente's miracle artificial hips

By Margaret Wente

Implant manufacturers are facing big class-action lawsuits

Eight years ago, I sat in a surgeon's office as he showed me X-rays of my deteriorating hips. He told me they were finished. I was only in my 50s, but I wasn't surprised. By the time I saw him, I could scarcely walk. I had skied and hiked and led a reasonably active life, but now I was a cripple. Sometimes I had to use the railings to drag myself hand over hand up the stairs.

Issue

- Currently, adverse events are reported using non-standardized metrics and do not account for sample size and length of follow up time
  - For example, 1% revision rate

- Comparisons between THA and HR outcomes are challenging due to:
  - Lack of standardized outcome measures
  - Study heterogeneity (e.g. follow up time, sample size)
  - Lack of analysis by device market status

Objectives

- We conducted a systematic review comparing HR to THA
- Standardized rates to an average per 1000 person years
  - Able to address gaps not previously addressed in published literature
  - Able to compare outcomes between THA studies that had longer-term follow-ups, to HR studies with limited follow-up

Methods

PICO Framework

- **Population**: adult patients (≥ 18 years)
- **Intervention**: primary HR
- **Comparison**: primary THA
- **Outcomes**: adverse events, safety issues or revision rates

Search strategy

- Studies were identified through the following electronic databases: MEDLINE, PubMed, EMBASE, the Cochrane Library, BIOSIS Previews, and Web of Science from 1997 to 2011

Inclusion criteria:

- English language studies reporting adverse events, complications, safety issues or revision rates for adults with primary hip OA, who underwent either primary HR or THA

Outcomes of interest:

- Revision, reoperation, dislocation, infection/sepsis, femoral neck fracture, time to revision, rates of early failure, mortality, and post-operative component alignment

JOINT REPLACEMENT REGISTRIES COMPARISON

- Revision rates were compared to rates from four joint replacement registries (JRR):

JRR	Year registry started	Number of primary hip procedures
Australia	1999	THA: 25,478 (2011) HR: 991 (2011)
New Zealand	1999	THA: 7218 (2011) HR: 142 (2011)
Sweden	1979	THA: 15,935 (2010) HR: 214 (2010)
England and Wales	2003	THA: 59,405-69,871 (2011) HR: 1801 (2011)

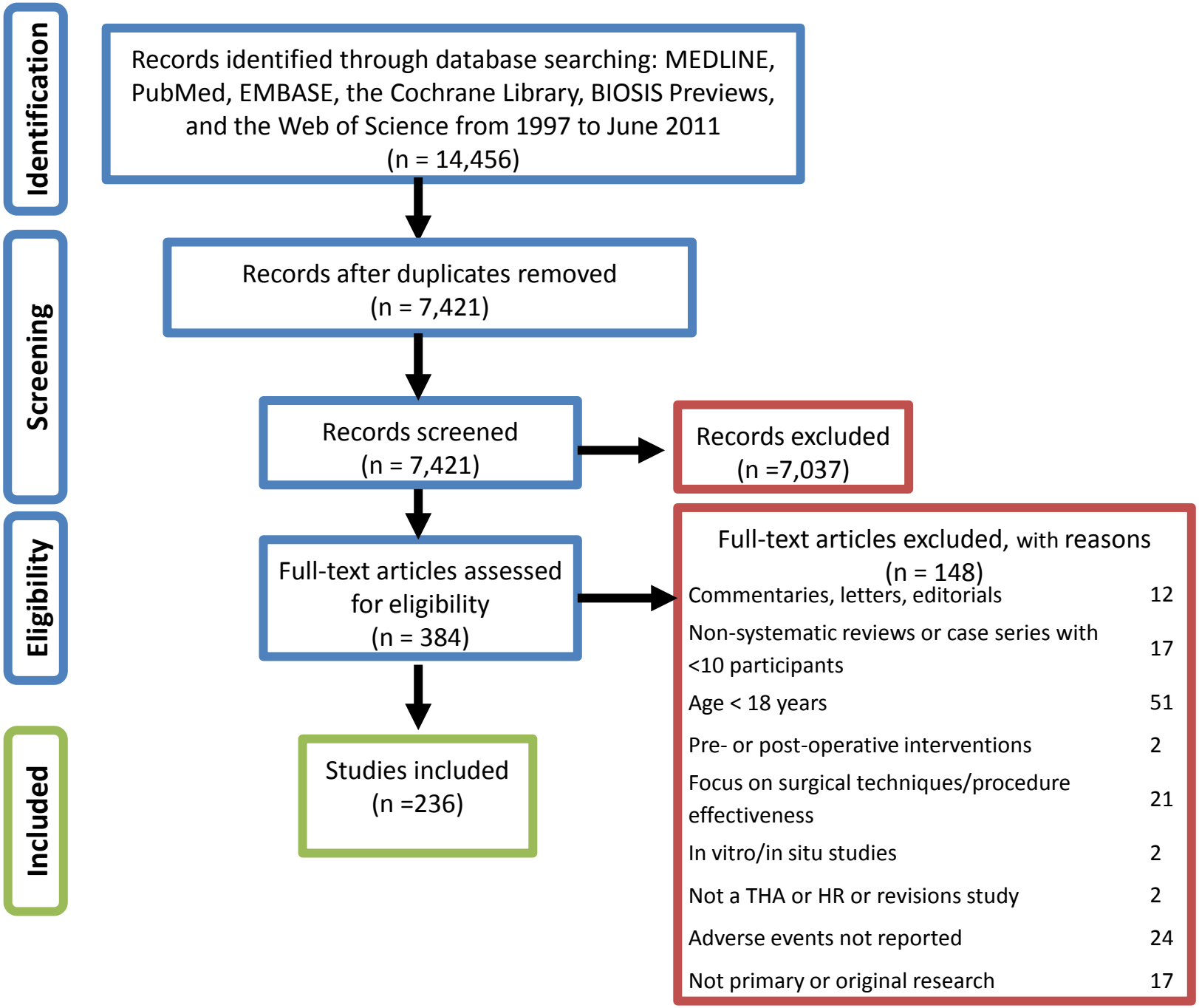
- These JRRs were chosen because they are members of the ISAR, have large sample sizes and are commonly used to reference adverse event rates

ISAR: International Society of Arthroplasty Registries

Analysis

- Results were standardized using weighted averages per 1000 person years and stratified by age, publication date and market status (in-use and discontinued)
- Prosthesis device types were extracted from each article and sorted by market status:
  1. All devices (both in-use and discontinued)
  2. Devices currently in-use
- Excluded studies that focused on specific subpopulations
  - e.g. revision specific, based on registry data, adults younger than 30 years, adults over 80 years, and obese populations/smokers

Results

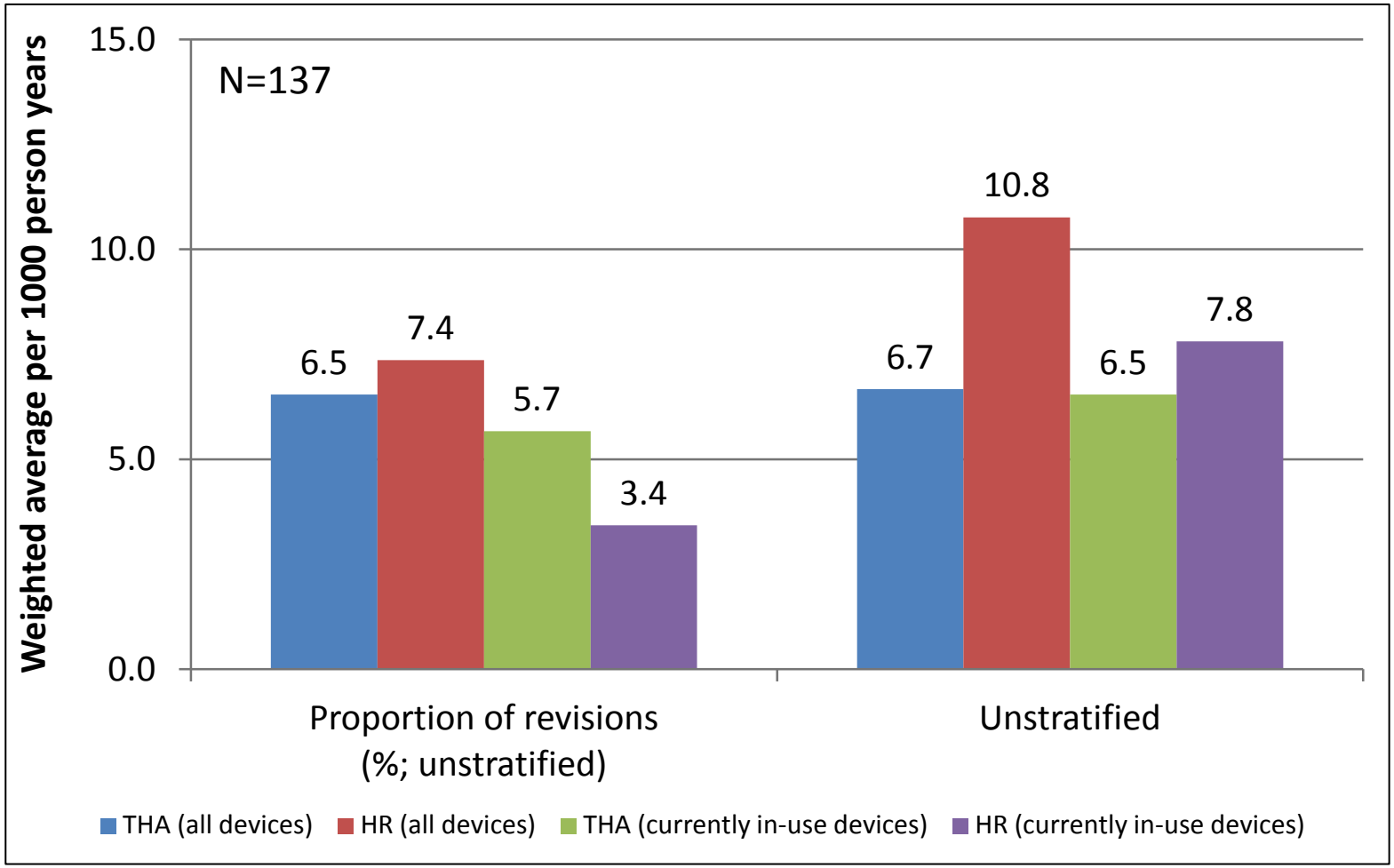

Identification
Screening
Eligibility
Included
Records identified through database searching: MEDLINE, PubMed, EMBASE, the Cochrane Library, BIOSIS Previews, and the Web of Science from 1997 to June 2011 (n = 14,456)
Records after duplicates removed (n = 7,421)
Records screened (n = 7,421)
Records excluded (n =7,037)
Full-text articles assessed for eligibility (n = 384)
Full-text articles excluded, with reasons (n = 148)
Commentaries, letters, editorials 12
Non-systematic reviews or case series with <10 participants 17
Age < 18 years 51
Pre- or post-operative interventions 2
Focus on surgical techniques/procedure effectiveness 21
In vitro/in situ studies 2
Not a THA or HR or revisions study 2
Adverse events not reported 24
Not primary or original research 17
Studies included (n =236)

Distribution of study designs for included articles

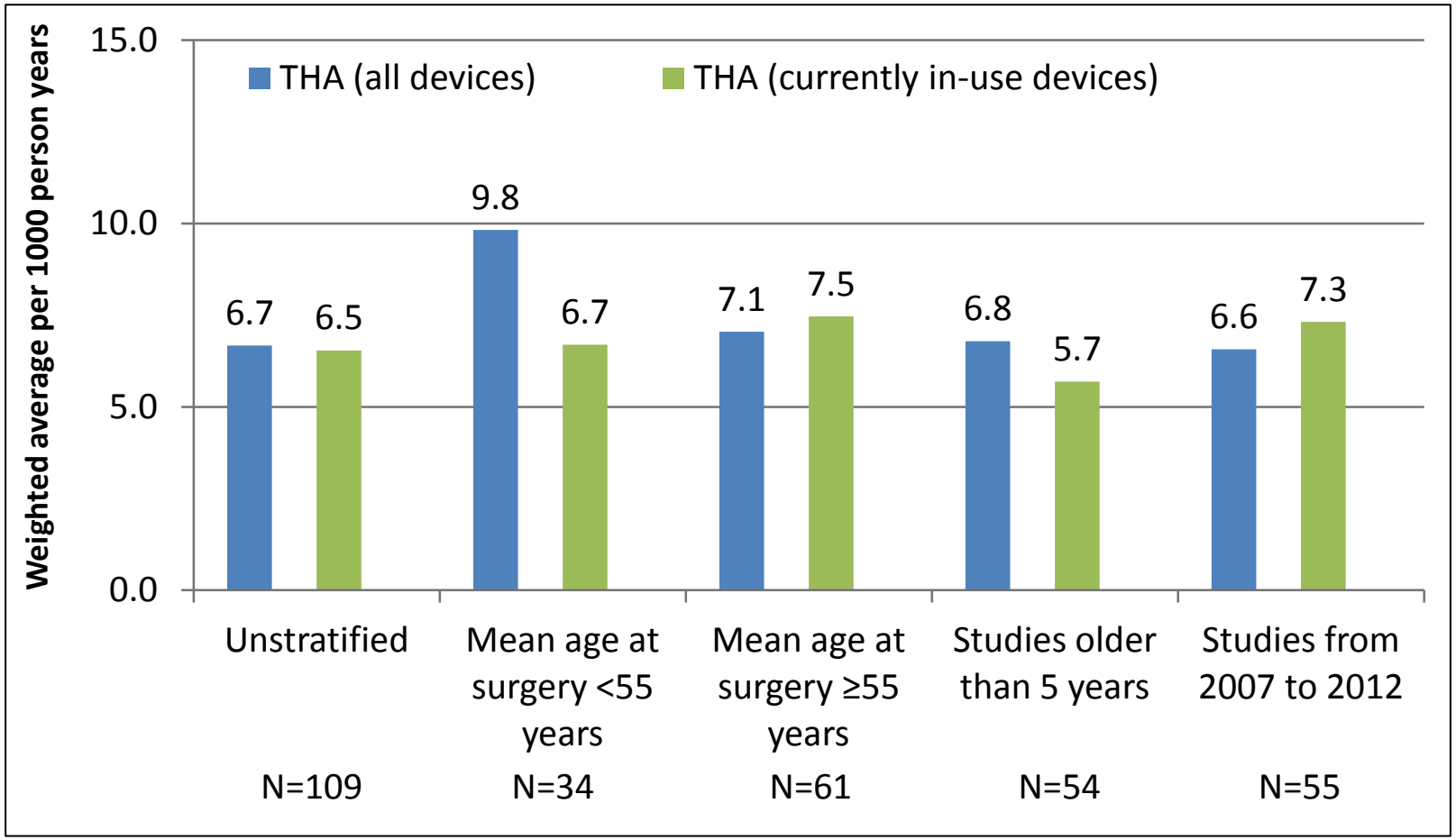
Only **6** of 17 RCTs were head-to-head comparisons!

Study Design	Number of Full-text Articles	
	N	%
Randomized control trial	17	7.2
Case control	14	5.9
Prospective cohort	110	46.6
Retrospective cohort	85	36.0
Prospective observational (multigroup)	4	1.7
Retrospective observational (multigroup)	4	1.7
Case series (with more than 10 participants)	2	0.8
TOTAL	**236**	**100**

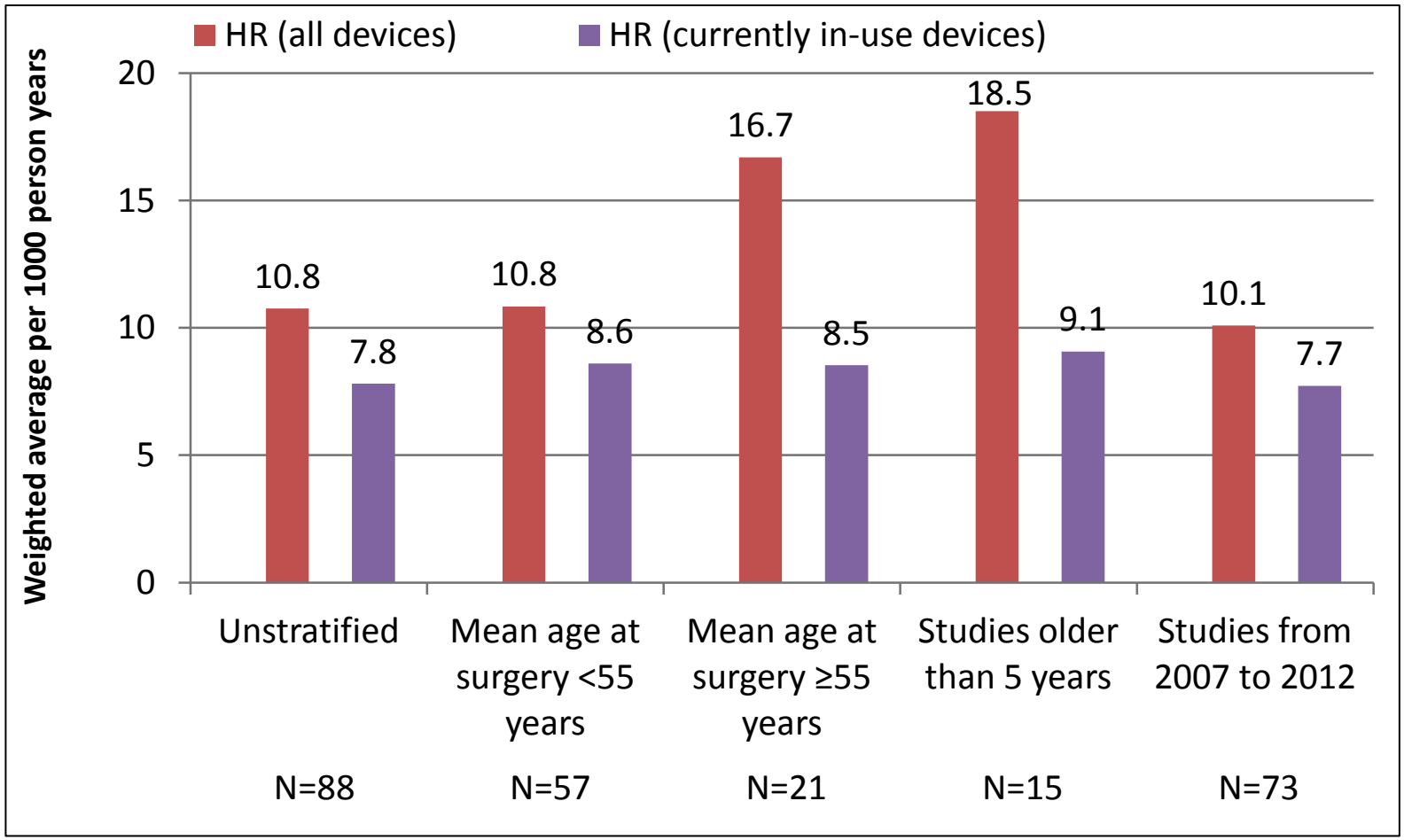
Average revisions per 1000 person years compared to the proportion of revisions in the same analyzed literature



Average revisions per 1000 person years comparing all **THA** devices (in-use and discontinued) and currently in-use **THA** devices



AVERAGE REVISIONS PER 1000 PERSON YEARS COMPARING ALL **HR** DEVICES (IN-USE AND DISCONTINUED) AND CURRENTLY IN-USE **HR** DEVICES



Average time to revision (years) and early revisions/reoperations (within 5 years of surgery)

	All devices (in-use and discontinued)		Currently in-use devices	
	THA	**HR**	**THA**	**HR**
Average time to revision (in years)	7.7	**3.0**	5.7	**2.9**
N	10	9	2	7
Early revisions/reoperations (within 5 years of surgery)	4.3	**11.3**	4.0	**10.3**
N	21	19	8	12

JRR REVISION RATES AFTER STANDARDIZING RATES PER 1000 PERSON YEARS (1)

Device	Australia	New Zealand	Sweden	England and Wales
THA	3.2	2.7	2.6	7.4
Revisions	6,321	2,278	27,134	6,104
Follow up time (years)	10	12	31	827,276 observed years
HR	4.6	2.4	4.1	14.2
Revisions	660	32	72	867
Follow up time (years)	10	12	10	61,170 observed years

JRR REVISION RATES AFTER STANDARDIZING RATES PER 1000 PERSON YEARS (2)

Device	Australia	New Zealand	Sweden	England and Wales	Our Study
THA	3.2	2.7	2.6	7.4	6.7
HR	4.6	2.4	4.1	14.2	10.8

Conclusions

Key findings vs. literature

- Revision and early revision/reoperation rates were higher in HR devices
  - Consistent with previous reviews of the literature[1,2,3,4]
- Time to revision (in years) has not been reported by other reviews of the literature comparing HR to THA[1,2,3,4]
- Adverse event definitions are not standardized throughout the literature

[1]Jiang et al. J Arthroplasty 2011; 26(3):419-426.
[2]Springer et al. J Arthroplasty 2009; 24(6 Suppl):2-8.
[3]van der Weegen et al. J Bone Joint Surg Br 2011; 93(3):298-306.
[4]Smith et al. Acta Orthop 2010; 81(6):684-695.

Strengths and Limitations

Strengths	Limitations
Used averages per 1000 person-years	Non-standardized definitions and study heterogeneity
Examined a large body of evidence	Under-reporting of prosthesis type
Analyzed results by market status	Some studies were not able to be grouped into market status categories
	Unable to examine gender differences

Conclusions (1)

- Revision rates are higher for HR and time to revision is shorter for HR
  - These findings should be taken into account when choosing patients for HR
- Revision rates change by removing discontinued devices from analyses
- Revision estimates differ between non-standardized and standardized reporting

Conclusions (2)

- Findings highlight importance of evaluating adverse event rates using standardized outcome metrics to account for exposure time and thus facilitate comparisons between studies
- Need to place greater emphasis on influence of market status when considering which prosthesis may be most beneficial
- Large-scale, long-term comparative studies and head-to-head RCTs that incorporate standardized outcome measures both pre- and post-operatively are needed
  - Also need to examine outcome differences by gender to inform which devices may be better for males or females

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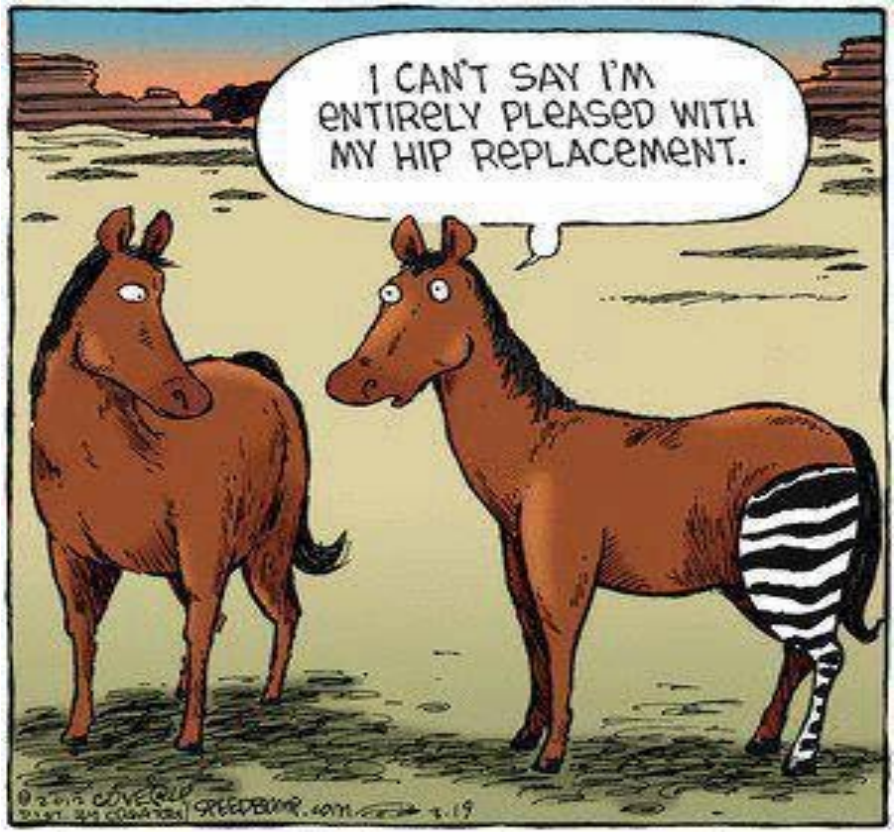

THANK YOU!

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Appendix Slides

Person years calculations

- Adverse events per 1000 person years in an individual study= ((AE)/(participants x T)) x 1000
  - Where:
    - AE = # of adverse events that occurred within the study population
    - participants = total # participants in the study population
    - T = mean follow-up time of the study

- Weighted average (by sample size)= $(w_1x_1+w_2x_2+\ldots w_nx_n)/(w_1+w_2+\ldots w_n)$
  - Where:
    - w = individual study sample size
    - x = individual study adverse event rate per 1000 person years

Comparison of weighted and un-weighted averages per 1000 person years using the outcome of revisions as an example

		All devices (both in-use and discontinued)		Currently in-use devices	
		THA	**HR**	**THA**	**HR**
Weighted Average		6.7	10.8	6.5	7.8
Un-weighted Average		10.4	18.7	9.5	10.3
	N	85	52	24	36

How revisions are reported in JRR annual reports

Device	Australia	New Zealand	Sweden	England and Wales
THA	Cumulative percent revisions at 10 years (6.2%)	Proportion of revisions relative to all THA primary implants (3.3%) over 12 years	Proportion of revisions relative to all primary implants (10-12%) over 10 years	0.74 revisions per 100 observed years
HR	Cumulative percent revisions at 10 years (7.5%)	Proportion of revisions relative to all THA primary implants (2.9%) over 12 years	Proportion of revisions relative to all primary implants (<1%) over 10 years	1.42 revisions per 100 observed years

Results: All adverse events

Summary of findings comparing market status group with results unstratified*

Adverse events (weighted average per 1000 person years)	All devices (both in-use and discontinued)		Currently in-use devices	
	THA	HR	THA	HR
Revisions	6.7	10.8	6.5	7.8
N	85	52	24	36
Reoperations	1.6	7.1	4.4	7.4
N	15	8	3	7
Dislocations	5.7	2.2	5.1	2.6
N	55	28	12	22
Infections/sepsis	2.2	2.3	4.4	1.8
N	43	30	10	22
Femoral neck fractures	3.0	5.7	1.3	6.3
N	7	22	2	15
The average time to revision (in years)	7.7	3.0	5.7	2.9
N	10	9	2	7
Early revisions/reoperation within 5 years of surgery	4.3	11.3	4.0	10.3
N	21	19	8	12

* Shading indicates the average per 1000 person years is higher within that market status group

- Revision, reoperation, and femoral neck fracture rates higher in HR devices
- Average time to revision is shorter for HR devices
- Dislocation rates are higher in THA devices