

Country Development and publication bias

A review of published studies

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Introduction:

- **Publication bias is the tendency to publish research results based on the strength and direction of findings**

Publication biases

- Language bias
 - Citation bias
- Multiple publication bias

What about location bias?

- The proportion of published articles from low income countries is lower than developed nations

There are several reasons

- **Poor methodological quality**
- **Less research projects**
- **Editorial bias**

What do researchers say?

- **Researchers from less-developed countries believe that there is a substantial editorial bias against their work**

The purpose of present study

- to compare the **methodological quality** and **statistical appeal** of published trials from countries with different developmental status

Methods



Selection criteria:

- Based on the **World Bank income criteria** countries were divided into:
 - Low
 - lower-middle
 - upper-middle
 - high income

Selection criteria:

- All records of clinical trials conducted in each income group during **1993** and **2003** were included if they:
 - **contained abstract**
 - **the number of study participants could be calculated from the abstract content.**

Search strategy:

- **Cochrane Central Register of Controlled Trials (2005, issue1) was searched.**
- **All trials including the names of countries in each income group in the Institution field of the records.**

The search strategy!

LOW INCOMES:

(Afghanistan or Angola or Bangladesh or Benin or Bhutan or Burkina Faso or BurkinaFaso or Burundi or Cambodia or Cameroon or (Central and African and Republic) or Chad or Comoros or Congo or Guinea or Haiti or India or Kenya or (Korea and Democrat\$) or Kyrgyz\$ or Lao or Lesotho or Liberia or Madagascar or Malawi or Mali or Mauritania or Pakistan or Rwanda or Sao Tome or SaoTome or Senegal or Sierra Leone or SierraLeone or (Solomon and island\$) or Somalia or Sudan or Tajikistan or Tanzania or (Timor and Leste) or Togo or Congo or (Cote and d'Ivoire) or Equator\$ or Eritrea or Ethiopia or Gambia or Ghana or Guinea or Moldova or Mongolia or Mozambique or Myanmar or Nepal or Nicaragua or Niger or Nigeria or Uganda or Uzbekistan or Vietnam or Yemen or Zambia or Zimbabwe).in.

LOWER MIDDLE INCOMES:

((Albania or Algeria or Armenia or Azerbaijan or Belarus or Bolivia or Bosnia or Brazil or Bulgaria or (Cape and Verde) or (China not hong kong) or Colombia or Cuba or Djibouti or Dominican or Ecuador or Egypt or (El and Salvador) or Fiji or (Georgia not USA) or Guatemala or Guyana or Honduras or Indonesia or Iran or Iraq or Jamaica or Jordan or Kazakhstan or Kiribati or Macedonia or Maldives or (Marshall and Island\$) or Micronesia or Morocco or Namibia or Paraguay or Peru or Philippines or Romania or (Russia\$ and Federation) or Samoa or Serbia or (South and Africa) or (Sri and Lanka) or Suriname or Swaziland or Syria\$ or Thailand or Tonga or Tunisia or Turkey or Turkmenistan or Ukraine or Vanuatu or (West Bank and Gaza)) not usa).in.

UPPER MIDDLE INCOMES:

((((American and Samoa) or (Antigua and Barbuda) or Argentina or Barbados or Belize or Botswana or Chile or Costa Rica or Croatia or Czech or Dominica or Estonia or Gabon or Grenada or Hungary or Latvia or Lebanon or Libya or Lithuania or Malaysia or Mauritius or Mayotte or Mexico or (Northern and Mariana and Island\$) or Oman or Palau or Panama or Poland or (Saudi Arabia) or Seychelles or Slovak or Venezuela or Uruguay or Trinidad or Tobago or (Vincent and Grenadines) or ((st or saint) and lucia) or ((st or saint) and kitts and nevis)) not usa).in.

HIGH INCOMES:

(Andorra or Aruba or Australia or Austria or Bahamas or Bahrain or Belgium or Bermuda or Brunei or Canada or (Cayman and Island\$) or (Channel and Island\$) or Cyprus or Denmark or (Faeroe and Island\$) or Finland or France or Polynesia or (Germany or Deutschland) or Greece or Greenland or Guam or (Hong Kong or hong-kong or hongkong) or Iceland or Ireland or Israel or Italy or Japan or (Korea and republic) or Kuwait or Liechtenstein or Luxembourg or Macao or Malta or Monaco or Netherland\$ or (new and Caledonia) or (new and Zealand) or Norway or Portugal or (Puerto and Rico) or Qatar or (San and Marino) or Singapore or Slovenia or Spain or Sweden or Switzerland or Emirates or (United Kingdom or Britain or England or uk) or (America or united states or USA) or (virgin and island\$)).in.

Sampling

- The systematic random sampling method to find **fifty articles** in each of four income group in years 1993 and 2003 separately
- A total of **400** records

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- All the citations identified by the above searches were screened and **animal studies, non interventional studies or conference abstracts** were excluded by consensus.

Data extraction:

Data were extracted by two reviewers on the:

- **language of publication**
- **use of randomization**
- **use of blinding (masking, placebo or sham)**
- **intent(ion) to treat analysis**
- **study sample size**
- **statistical significance**

Data extraction (cnt'd):

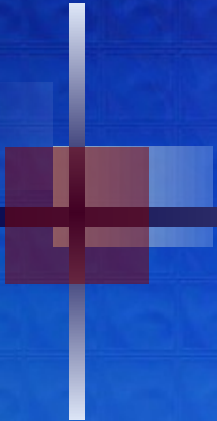
The results of a trial was called significant when:

- there was at least a $p < 0.05$
- the 95% confidence interval excluded 0
- the statistical significance was stated in the results section



Journal impact factors were obtained from
the 1994 and 2003 editions of the
**Science Citation Index Journal Citation
Reports**

Results



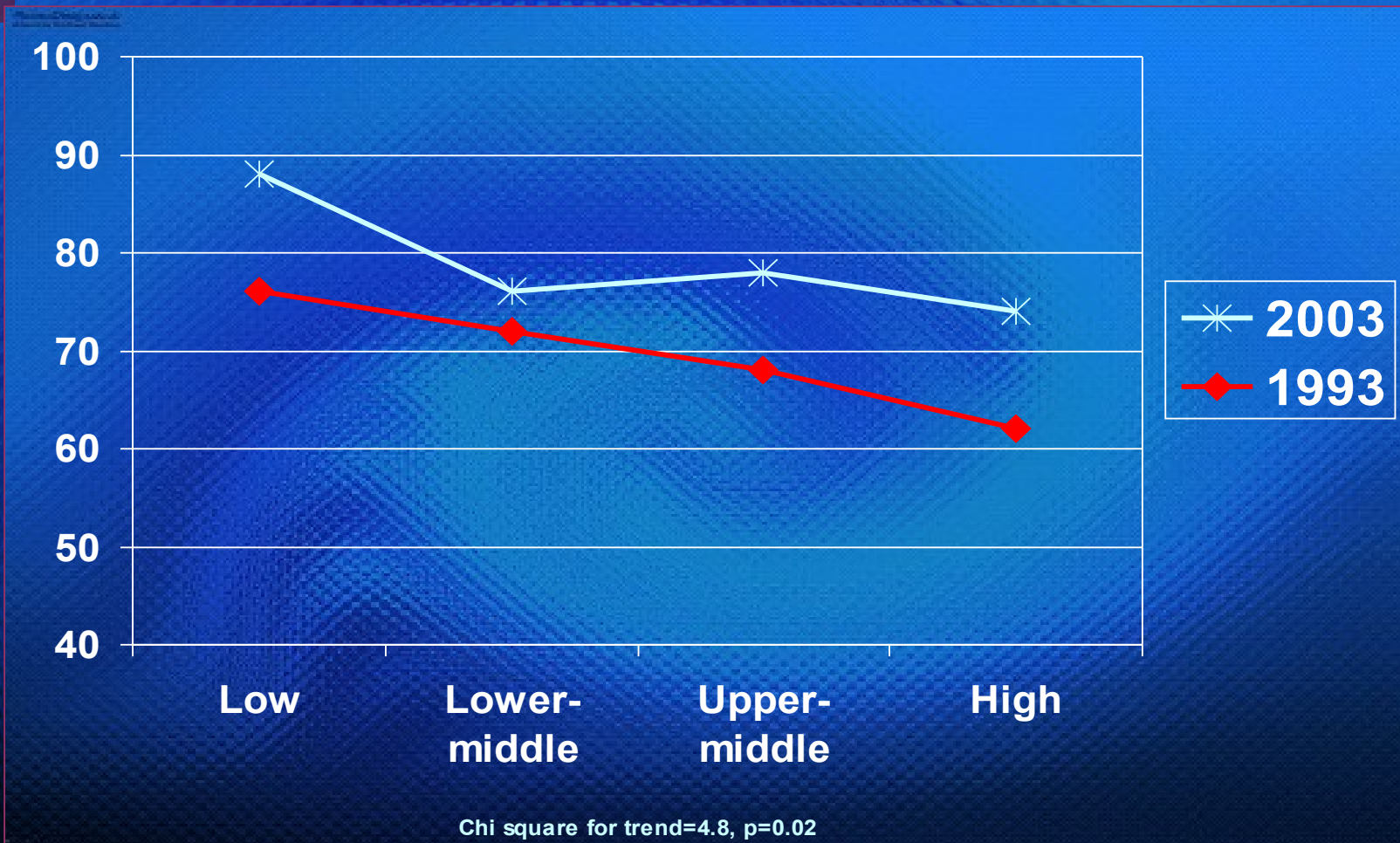
The characteristics of studies

- 377 (94.3%) English language articles
- 384 (96%) Controlled Clinical Trials
- 298 (74.5%) Randomized Controlled Trials
- 141 (35.3%) Double-blind method
- 39 (9.8%) single-blind method

The characteristics of studies

- The loss to follow-up percent was stated in **29** abstracts
- **Five** studies reported an intention-to-treat analysis.

The percentages of Randomized Controlled Trials:



High income countries V.S. other nations

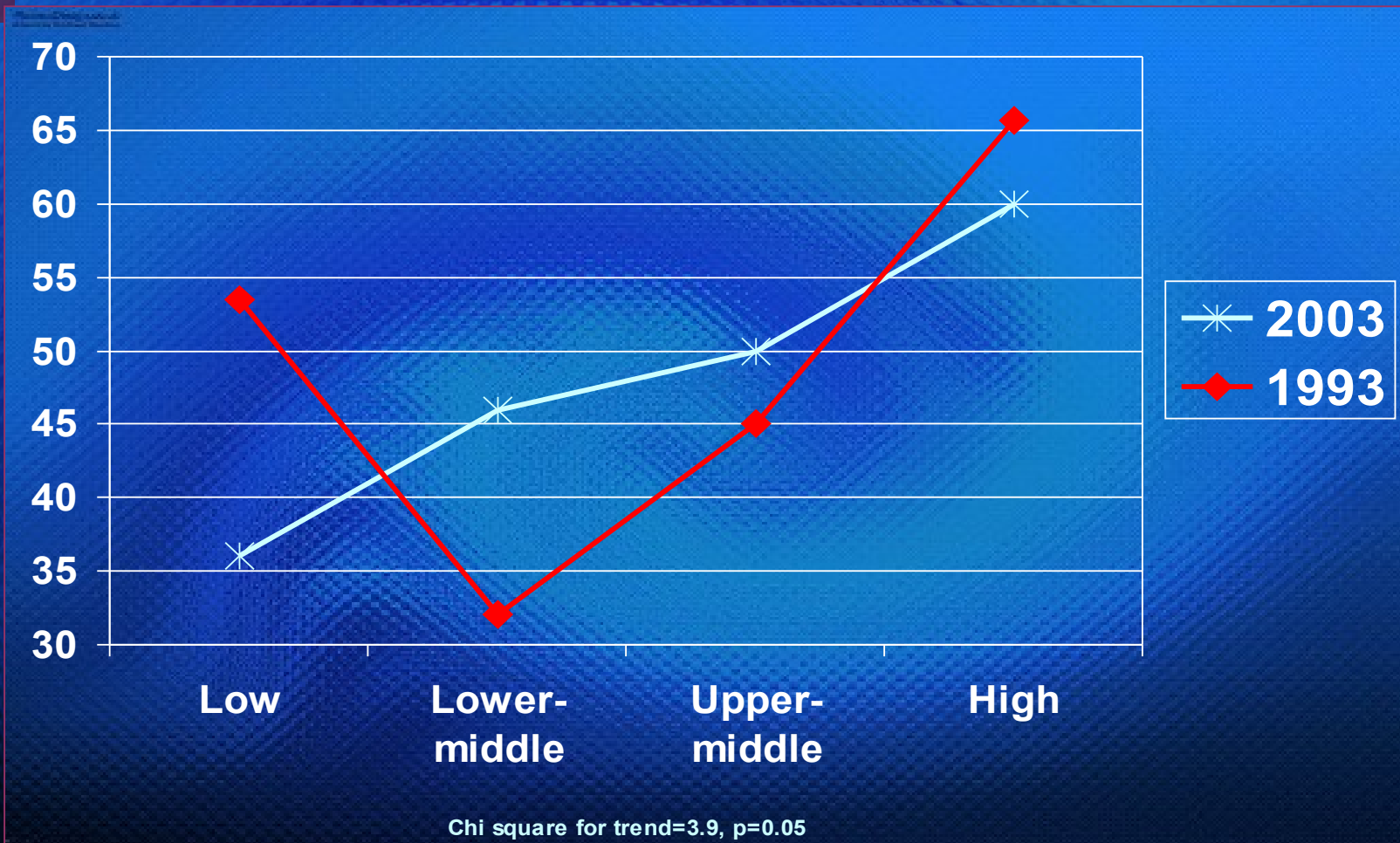
Adjusted OR(95% CI)

Randomization:

1993	0.59 (0.29 to 1.17)
2003	0.64 (0.29 to 1.36)

adjusted for the language of publication

The percentages of Blinded studies:



High income countries V.S. other nations

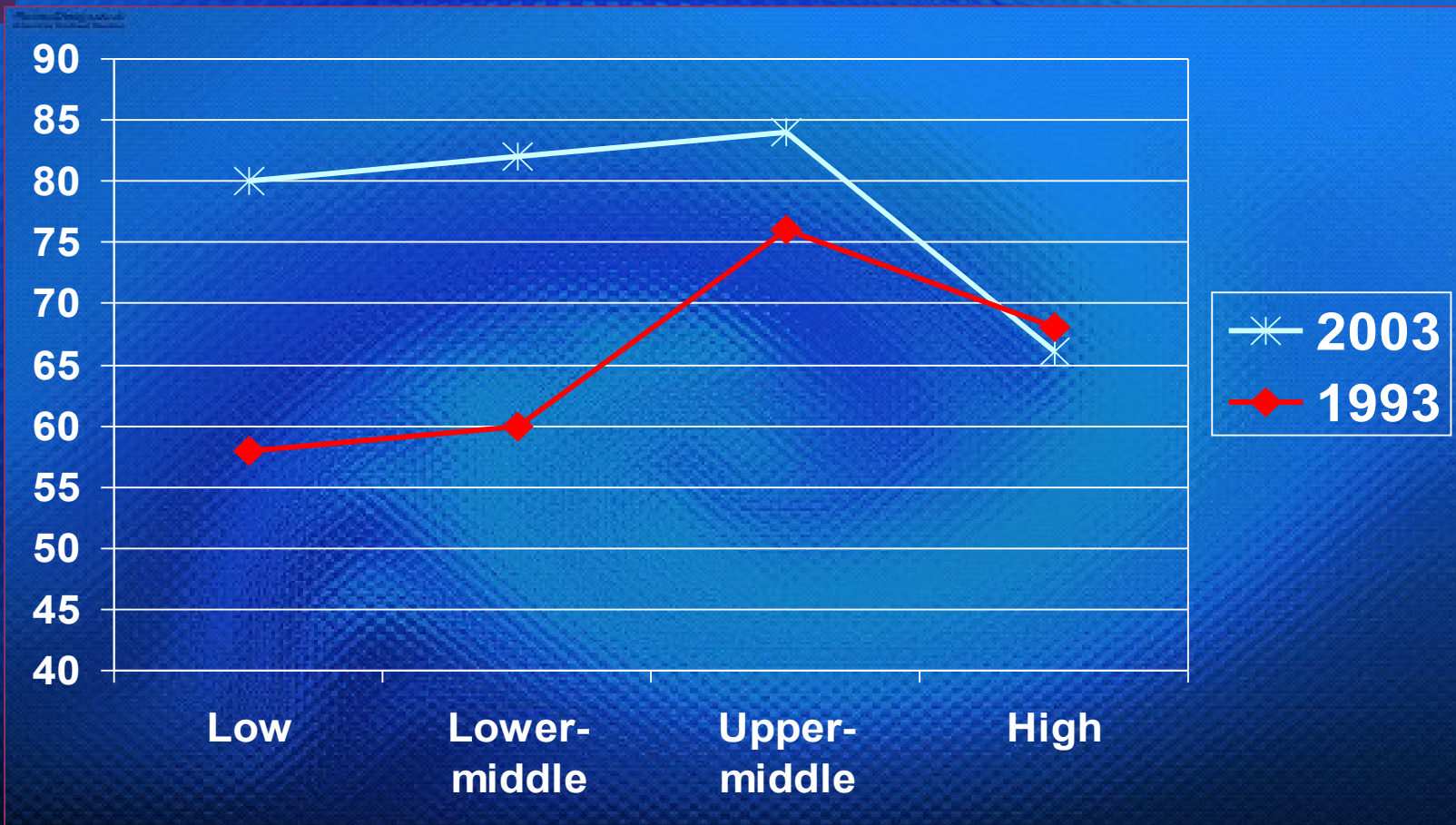
Adjusted OR(95% CI)

Blinding:

1993	1.93 (0.99 to 3.74)
2003	2.36 (1.08 to 5.13)

adjusted for the language of publication

The percentages of Significant results:



Chi square for trend=0.02, p=0.88

High income countries V.S. other nations

Adjusted OR(95% CI)

Statistical Significance:

1993	1.17 (0.58 to 2.34)
2003	0.41 (0.20 to 0.85)

adjusted for the language of publication

Journal impact factor:

Forward stepwise linear regression model:

Dependent variable:

- Journal impact factor

Independent variables:

- **country income**
- language of publication
- study sample size
- publication year
- Randomization
- Blinding
- statistical significance

Journal impact factor:

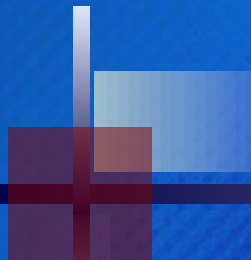
Forward stepwise linear regression model:

Dependent variable:

- Journal impact factor

Significant Independent variables:

- **country income**
- **language of publication**
- **study sample size**
- **publication year**
- Randomization
- Blinding
- statistical significance

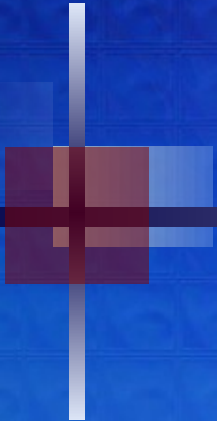


Explanatory variables*	B coefficient(95% CI)	t statistic	pvalue
Country income	0.490(0.249 to 0.730)	4.00	<.0001
Publication year	0.269(0.060 to 0.479)	2.52	.012
Log Study sample size†	0.197(0.103 to 0.291)	4.11	<.0001
Language of publication	0.976(0.247 to 1.70)	2.63	.009

**The randomization, use of blinding and statistical significance were not selected in the final forward stepwise regression model.*

†Logarithmic transformation because of a large right skewness.

Discussion



Main finding

- The frequencies of **methodological quality** and **statistical appealing** indicators in the published articles from lower income nations have increased more than developed countries during the past ten years.

Probable reasons

- The development process
- Enhancement of exclusive use of critical appraisal checklists by the editors of western journals

Bias against the diseases of poverty in the literature

- The editorial board members of international medical journals
- The studies enrolling some participants from the United States
- Negative findings in a local journal (language bias)

- The effect of country development on the odds of publication of the significant results was significant after adjustment for the language
- The independent effect of country development

Something more than a language bias

Journal impact factor

- No significant relationship with **methodological quality indicators**
- Significant relationship with **study sample size** and **country income**

ALARM SIGN

Developing country bias

We suggest...

- The “Developing country bias” should be intentionally stated as an independent factor
- The current standards for reporting trials should be enforced more consistently

Study limitations

- The study presents no data on the total number of papers submitted
- All assessments are done based on the data provided in title, abstract and keywords
- We limit our investigation to clinical trials
- The Cochrane Central Register of Controlled Trials (CENTRAL) as the source of studies



Thank You!

Any Question?