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Annual Report on Sex in Preclinical Studies – ATVB Publications in 2018

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To comply with the National Institutes of Health (NIH) guidelines for rigor and reproducibility on reporting sex as a biological variable, the editors of ATVB previously reviewed 295 preclinical articles published in ATVB 2017 and 2016 and provided detailed analysis on “Reporting sex and sex differences in preclinical studies” (Published in the October issue of 2018¹). The editors have decided to continuously monitor and document the analytic results of reporting sex and sex differences in ATVB on an annual basis. Here we provide the annual report of 2018 in this Recent Highlights series.

A total of 186 preclinical science research articles^{2–187} published in 2018 were reviewed by the editors. Twenty-five articles were excluded for further analysis because they only studied human samples or cell lines. There were 6 species reported in the rest 161 articles (Table 1), including zebrafish, mouse, rat, rabbit, pig, and nonhuman primates. Among these 161 articles, 6 articles only studied embryos or neonates. Therefore, 155 publications with in vivo animal studies on reporting sex were analyzed.

In 2018, one hundred and forty five articles (94%) reported sex for in vivo models, compared to 92% and 79% of those published in 2017 and 2016, respectively. Among all

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species, 28% reported studies from both male and female animals, compared to 21% and 11% of publications in 2017 and 2016, respectively. Eighty two of the 155 articles (53%) articles reported primary cells isolated from either mouse or rat. Forty nine of the 82 articles (60%) reported sex, whereas 27% articles published in 2017 and 28% in 2016 provided sex information for primary cells. Eight articles in 2018 and 2 in both 2017 and 2016, respectively, reported cells from both male and female animals.

For in vivo studies among the 161 publications in 2018 (Table 1), 4 articles reported data from zebrafish during embryonic development, 4 articles studied rabbits with 3 reporting only male data and one did not define the sex that was studied, 1 article studied both male and female pigs, 2 articles studied non human primates with one reporting only male data and one reporting both male and female data.

Rodents are the predominantly used species, with most publications using mice and a lesser number using rats. Of the 161 articles published in 2018, 142 (88%) reported mouse models, and 8 (5%) reported rat models. For in vivo studies, 132 (94%) of 140 articles reported sex in mouse models after excluding 2 articles that only studied embryos or neonates, and 7 of 8 (88%) articles reported sex in rat models. For primary cells, 44 of 74 (59%) articles reported sex in mice, and 5 of 8 (63%) articles reported sex in rats.

For mouse studies (Table 2), 78 of 140 (56%) articles published in 2018 reported data only from male mice, 12 (9%) articles reported data only from female mice, and 42 (30%) reported data from both male and female animals. Among the 90 articles that only studied one sex, 39 (43%) provided a brief justification why only one sex was studied in mice. For the 8 rat studies, 7 (88%) articles reported data only from male rats, and 1 article did not provide the sex information.

On the basis of this data analysis, three significant improvements were noted in the 2018 publications, compared to the publications in 2017 (Figure 1). First, more animal studies provided a justification why a specific sex (either male or female) were used. Second, more studies reported data derived from both male and female animals. Third, increased number of articles reported the sex of primary cells isolated from animals. The latter improvement is largely attributed to the implantation of Major Resources Tables started in the late 2018.

Table 2 shows clearly that most animal studies published in 2018 reported data only from male animals (89 articles for male versus 12 articles for female), similar to the publications in 2017 (75 articles for male versus 18 articles for female). The major reason the authors stated for studying only male animals is that the short estrus cycle in murine females may have confounding effects on data interpretation. Many provided literature evidence that estrogen had effects on the physiological or pathophysiological phenotype, while some did not provide solid evidence to support their use of male animals. Other reasons include (1) previous studies in the literature or the authors' laboratory showed that female animals had milder effects on cardiovascular diseases; (2) the literature has exclusively reported data only from male mice; (3) previous studies did not note sexual dimorphism; or (4) the authors have studied the same sex in their previous studies and they hope to be consistent with their previous study designs. For the articles that only studied female animals, the authors state

that (1) male animals tend to show aggressive behavior; (2) no sex difference was found, but female animals were easier to handle; (3) female animals had more severe disease; or (4) female had more modest phenotype. Among the 44 articles that reported both male and female animals, two articles found sex difference, which opened a door for the authors to understand sex-related mechanisms.

The editors acknowledge the significant improvement on reporting sex in most preclinical studies published in 2018. The editors also acknowledge that experimental designs and reporting sex in preclinical studies still need to be improved. For example, for articles that reported both male and female data, many studies pooled data from male and female animals. Some stated this approach was appropriate because male and female animals had no sex difference, whereas some did not provide a reason. The editorial process has now modified to require analysis of data in a sex specific manner. Pooling of data from both sexes may be permitted following the demonstration of no statistically significant difference between the two sexes.¹⁸⁸ ATVB will continuously take efforts in encouraging the authors to report both sexes and analyze data from each sex separately to enhance opportunity to explore sex difference. In addition to the ATVB Technical Review mechanism and the editors' annual review, the editors hope that more authors spontaneously study both sexes to explore new mechanisms of sex-mediated cardiovascular functions and diseases.^{1,189}

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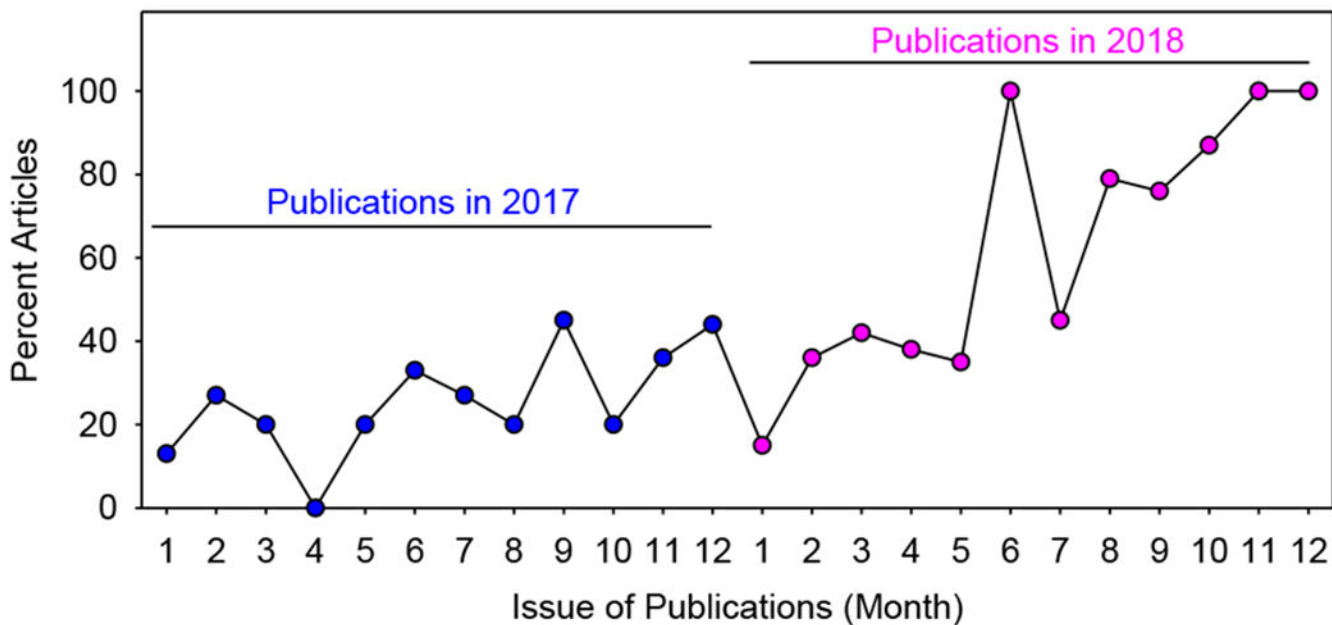


Figure 1: Percent of articles that reported both sexes or provided a justification why only one sex was studied.

ATVB Publications of preclinical research in 2017 and 2018 were analyzed. X axis represents the month of publications. Y axis represents percent of monthly publications that either reported data from both male and female animals or provided a justification why the authors only studied a specific sex.

Table 1.

Reporting Sex of Animals in Preclinical Studies of ATVB Publications in 2018

Species	Total Article Number	Reporting Sex Number (%)	Reporting Both Sexes Number (%)
Zebrafish	4	-	-
Mouse	142	132 (94%)	42 (30%)
Rat	8	7 (88%)	0
Rabbit	4	3 (75%)	0
Pig	1	1 (100%)	1 (100%)
Primate	2	2 (100%)	1 (50%)

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Table 2.

Percent of Articles Reporting Sex in Mouse Studies of ATVB Publications in 2018

Reporting Sex	Articles (Number)	Articles (%)
Male	78	56
Female	12	9
Both Male and Female	42	30

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