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What is the gender representation in authorship in later phase systemic clinical trials in biliary tract cancer (BTC)? - a retrospective review of the published literature

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ABSTRACT

Objectives Female physicians in medicine are increasing, but disparities in female authorship exist. The aim of this study was to characterise factors associated with female first (FF) and female senior (SF) authorship in later phase systemic oncological clinical trials in biliary tract cancer (BTC) and identify any changes over time.

Setting Embase/Medline identified trial publications in BTC (2000–2020) were included. χ2 tests and log regression were used (assessed factors associated with FF and SF authorship, including changes over time (STATA V.160).

Primary outcome measure FF and SF authorship in later phase systemic oncological clinical trials in BTC.

Secondary outcome measure Any changes over time?

Results Of 501 publications, 163 met inclusion criteria. The median percentage of female author representation in publications was 25%; there were no female authors in 13% of publications. Geographic location of the home institution of the first and senior authors was Asia (42%/42%), Europe (29%/29%), USA (24%/22%) and other (4%/6%), respectively. Overall, FF and SF author representation was 20% and 10%, respectively. The median position of the first female author was second in all the publication author lists. The phase of trial, journal-impact factor, industry funding or whether the study met its primary endpoint did not impact FF/ SF author representation. More SF authors had home institutions in ‘other’ geographic locations (40% in 10 trials) (p=0.02) versus Asia (6%), Europe (8%) and USA (14%). There were no significant changes in FF/ SF representation over time (p=0.61 and p=0.33 respectively).

Conclusions FF and SF author representation in later phase systemic clinical trial publications in BTC is low and has not changed significantly over time. The underlying reasons for this imbalance need to be better understood and addressed.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ While gender differences in lead authorship positions have been reported in a variety of medical and surgical specialties, these differences have not been reported to date in systemic therapy trials in biliary tract cancer.

⇒ Embase and Medline were used to identify trial publications in biliary tract cancer over a 20-year period and carried out by a librarian with expertise in comprehensive search strategies.

⇒ The proportion of women specialising in biliary tract cancer (systemic) academic oncology is not known, and, therefore, one cannot comment definitively on whether the values for female first and senior author representation in later phase systemic clinical trial publications are proportional to the numbers of female providers practicing in this field.

INTRODUCTION

The proportion of women in medicine is increasing (approximately 50% in the medical school/workforce in the USA and United Kingdom), but disparities in female authorship in oncology research publications exist.1,2 Scientific publications are an important metric of academic productivity and expertise,3 and research and trial leadership affects promotion and tenure, prominence in the field, and access to potential funding opportunities.

The common guidance for assigning authorship in medical practice and in the biliary tract cancer (BTC) speciality aligns with what has been reported by Baerlocher et al;5 in relation to categories of contribution, the levels of participation are highest for first authors, followed by last and then second authors in
original research articles. Middle authors generally have lower levels of contribution particularly in conception, drafts of the manuscript, supervision and being a guarantor. Female authorship in leading positions such as first, senior or corresponding has been historically low in multiple medical and surgical specialties. In a study examining gender differences in corresponding authorship in manuscripts of randomised oncological clinical trials, the rate of female corresponding authorship was 7.2% in gastrointestinal cancers and 7.9% in gastrointestinal cancers. In another study examining female authorship in major academic gastroenterology journals (Gastroenterology, Hepatology, American Journal of Gastroenterology, Clinical Gastroenterology and Hepatology and Gastrointestinal Endoscopy) over a 20-year period, female first and senior authors increased from 9.1% to 29.3% (p<0.0001) and from 4.8% to 14.5% (p<0.0001), respectively, from 1992 to 2012. It was concluded that female first authorship occurred at the expected proportion, but those in the senior author position was less than expected, based on the proportion of female academic gastroenterologists.

In addition, an observational study examined changes in representation of women among first authors of original research published in high-impact general medical journals (Annals of Internal Medicine, Archives of Internal Medicine, The BMJ, JAMA, The Lancet, and the New England Journal of Medicine (NEJM)) over a 20-year period from 1994. Women in the first author position increased significantly from 27% in 1994 to 37% in 2014 (p<0.001). However, female first authorship decreased over the years in the NEJM and also seemed to decline in The BMJ but started substantially higher (approximately 40%), with the article authors concluding that the under-representation of research by women in high-impact journals was an important concern.

One survey of international hepatopancreaticobiliary (HPB) fellowship programmes reported that women represented 11% of 351 HPB surgeons trained over a 25-year period, and membership surveys of the Americas Hepato-Pancreato-Biliary Association included responses that were from over 90% men. Despite this, analysis of authorship in articles related to HPB surgery revealed that the number of female first authors increased from 15.6% in 2008 to 25.7% in 2018 (p<0.001), while the proportion of senior female authors did not change significantly: 7.8% in 2008 and 10.1% in 2018 (p=0.15).

In general, the rates of female first and senior authorship in academic general medical, surgical, paediatric and obstetric journals have increased. While gender differences in lead authorship positions have been reported in a variety of medical and surgical specialties, these differences have not been reported to date in systemic therapy oncological trials in BTC. Practice-changing research in BTC has more recently increased, and, thus, authorship positions have the potential to impact the respective careers of those authors. As scholarly output remains a critical component of academic advancement, this study aimed to describe and assess factors associated with female first and senior authorship (last listed) in later phase systemic clinical trials in BTC (which are positions perceptually considered more influential for career progression) and to identify any changes over a 20-year period (2000–2020). Awareness of any potential disparities in this disease group specialty, and indeed others, may empower change, if required.

**METHODS**

**Study eligibility**

Eligible studies included final primary peer-reviewed manuscript publications of prospective phase II and III clinical trials involving systemic therapy in BTC published from 2000 to 2020 (including cholangiocarcinoma, gall bladder cancer, ampulla of Vater cancer) in the English language. The following were excluded: secondary trial publications, reviews/meta-analyses, mixed tumour-type studies, non-biliary tract tumour sites, reports on benign disease, phase I (often mixed tumour types or expected to move to later phase and less influential for academic progression)/pilot/feasibility studies, non-systemic/radiology studies, translational substudies, editorials/guidelines/highlights/author reflections, case reports, trials in progress publications, and retrospective studies.

**Search strategy**

The Medline and EMBASE databases were used to identify final primary trial publications in BTC. The years 2000–2020 were chosen to represent 10 years pre and postpublication of the first practice-changing randomised phase III systemic clinical trial in advanced biliary cancer (ABC-02). The ABC-02 trial led to cisplatin/gemcitabine being adopted worldwide as the standard of care first-line palliative chemotherapy regimen choice. Prior to ABC-02, there was no standard of care first-line option in this setting. This trial provided the reference standard for future trials and highlighted that large trials in rarer population subgroups were possible. The search was last updated on the 11 August 2020 and was carried out by a librarian with expertise in comprehensive search strategies (coauthor T). The following Medline and EMBASE search strategy was employed: (1) (“biliary tract” OR gallbladder OR “bile duct*” OR klatksin).ti,ab, (2) exp “BILARY TRACT”/, (3) (1 OR 2), (4) (cancer* OR carcinoma* OR tumor* OR tumour* OR carcinoma* OR neoplas* OR malign*).ti,ab, (5) (3 AND 4), (6) exp “BILIARY TRACT NEOPLASMS”/, (7) exp CHOLANGIOCARCINOMA/, (8) (5 OR 6 OR 7), (9) (“phase 2” OR “phase ii” OR “phase 3” OR “phase iii”).ti,ab, (10) (8 AND 9), (11) 10 [DT 2000–2020].

**Data extraction**

The first author (MMN), whose speciality interest is BTC, reviewed all publication titles and abstracts for eligibility and final published manuscripts meeting inclusion criteria were considered in detail. The following 12 data items were collected: (1) gender and proportion of male/
female authors (denominator being the authors included in publications of prospective phases II and III clinical trials involving systemic therapy in BTC from 2000 to 2020), (2) primary disease site (all BTC (including cholangiocarcinoma, gall bladder cancer, ampulla of Vater cancer)/BTC non-specified or gallbladder cancer alone or cholangiocarcinoma alone), (3) treatment setting (neoadjuvant/adjuvant, first-line advanced, post-first-line advanced, advanced (non-specified), (4) treatment modality received (systemic therapy (including chemotherapy and/or immunotherapy), targeted therapy alone, localised therapy in combination with systemic therapy), (5) phase of trial (single-arm phase II, randomised phase II, randomised phase III). In addition, the geographic location (6) of the home institution of the first/senior author (Asia, Europe, USA, another location (Australia, Canada, Africa, South America)) was collected. Whether the trial met its primary endpoint or not (7) was also collected, (8) whether the trial was industry funding (yes/no/unknown), (9) year published (2000–2020) or (10) whether published pre/post ABC-02. The impact factor (IF) of journal was also recorded (11) (the 2020 IFs, as reported in the Journal citation reports were used (Clarivate Analytics); it was not possible to determine journal IF at the time of publication and relatively comparable inflation over time was assumed). The binary IF (12) of journal (≤20 vs >20) and varying cut-offs (0 ≤5, >5 ≤10, >10 ≤15, >15 ≤20, >20 ≤30, >30 were evaluated, as a number of potentially important BTC trials may be published in lower impact journals due to being a rarer disease group, and, thus, these publications could still have an influential impact on author career trajectory) were extracted. Documented speciality of first and senior authors (Medical Oncology/Surgical Oncology), were also documented.

Gender was determined by inspection of first names, where gender was not known through personal knowledge of the authors, the following search engines/sources were used to try to determine gender: internet/google search, including review of institutional profiles, portfolios and images, LinkedIn, Research Gate profiles and direct communication with the corresponding or other coauthor. Academic rank, qualifications, equally contributing authors and whether authors were principal/chief investigators were not available.

**Statistical analysis**

Frequency and percentages are reported for categorical variables, as well as medians for continuous variables. Due to the rarity of a BTC diagnosis, later phase systemic oncological trials require multi-institutional and frequently global collaborative involvement, and, therefore, observations are expected to be predominantly independent. χ² tests and log regression were used to assess factors associated with female first and female senior authorship, including changes over time (2000–2020). Differences were considered to be statistically significant at <0.05. Log regression was performed of the factors associated with female first and female senior authorship, if the χ² p value was <0.05. Statistical analysis was performed using the statistical software package, STATA V.16 (Stata Corporation, College Station, Texas).

**RESULTS**

Of 501 publications, 163 met the inclusion criteria (figure 1). There were 130 (80%) single-arm phase II and 24 (15%) and 9 (5%) randomised phase II and III trials, respectively; 119 (73%) studies enrolled ≤50 patients. The tumour primary sites included were all BTC: 140 (86%), cholangiocarcinoma: 13 (8%) and gallbladder cancer, 10 (6%); 133 (80%) involved chemotherapy, 21 (13%) targeted therapy and 9 (5%) localised/systemic therapy combinations.

One hundred and six studies (65%) were in the first-line advanced setting, 28 (17%) post-first-line, 21 (13%) advanced non-specified and 8 (5%) in the neo-adjuvant/adjuvant setting. Fifty-five (34%) received industry funding and 106 (65%) studies met their primary endpoint (table 1).

One hundred and five (64%) were published post-ABC-02. The publication IF was ≤5 in 50% and >20 in 12%. There were 1915 total authors included in the 163 publications. There were 153 unique first and last authors; 32 unique female first authors (none with more than one first authorship) and 17 unique female last authors (none with more than one last authorship). There were six and four male authors who had more than one first and senior author publication, respectively. The median number of authors in all publications was 11. Among 113 trials where
Table 1  Factors associated with female first and senior authorship in phase II/phase III systemic oncological clinical trial publications in biliary tract cancer

| Trial characteristics                          | Number (N) (%) | Female first author, N (%)* | Female first author, P value | Female senior author, N (%)† | Female senior author, P value |
|-----------------------------------------------|----------------|-----------------------------|------------------------------|-----------------------------|-------------------------------|
| Disease site (N=163):                         |                |                             |                              |                             |                               |
| All BTC/BTC non-specified 140 (86)            |                | 29 (19)                     | 0.24                         | 13 (8)                      | 0.45                          |
| Cholangiocarcinoma 13 (8)                     |                | 3 (2)                       |                              |                             |                               |
| Gallbladder cancer 10 (6)                     |                | 0 (0)                       |                              |                             |                               |
| Treatment setting (N=163):                    |                |                             |                              |                             |                               |
| Neo-adjuvant/adjuvant 8 (5)                   |                | 0 (0)                       | 0.26                         | 0 (0)                       | 0.38                          |
| First-line advanced 106 (65)                  |                | 23 (15)                     |                              |                             |                               |
| Post first-line advanced 28 (17)              |                | 3 (2)                       |                              |                             |                               |
| Advanced (non-specified) 21 (13)              |                | 6 (4)                       |                              |                             |                               |
| Treatment modality (N=163):                   |                |                             |                              |                             |                               |
| Systemic therapy (chemotherapy/immunotherapy) | 133 (82)       | 27 (18)                     | 0.77                         | 14 (9)                      | 0.37                          |
| Targeted therapy 21 (13)                      |                | 3 (2)                       |                              |                             |                               |
| Localised therapy 9 (5)                      |                | 2 (1)                       |                              |                             |                               |
| Phase of trial (N=163):                       |                |                             |                              |                             |                               |
| Single arm phase II 130 (80)                  |                | 27 (18)                     | 0.67                         | 16 (10)                     | 0.26                          |
| Randomised phase II 24 (15)                   |                | 4 (3)                       |                              |                             |                               |
| Randomised phase III 9 (5)                    |                | 1 (1)                       |                              |                             |                               |
| Geographic location of trial (N=163):         |                |                             |                              |                             |                               |
| Asia 69 (42)                                  |                | 10 (7)                      | 0.43                         | 4 (3)                       | 0.02                          |
| Europe 48 (29)                                |                | 11 (7)                      |                              |                             |                               |
| USA 36 (22)                                   |                | 6 (4)                       |                              |                             |                               |
| Other‡ 10 (6)                                 |                | 4 (3)                       |                              |                             |                               |
| Met primary end-point (N=163):                |                |                             |                              |                             |                               |
| Yes 106 (65)                                  |                | 22 (15)                     | 0.61                         | 11 (7)                      | 0.94                          |
| No 57 (35)                                    |                | 10 (7)                      |                              |                             |                               |
| Trial industry funding (N=115):               |                |                             |                              |                             |                               |
| Yes 55 (34)                                   |                | 8 (5)                       | 0.59                         | 8 (5)                       | 0.08                          |
| No 60 (37)                                    |                | 11 (7)                      |                              |                             |                               |
| NA 48 (29)                                    |                | 13 (9)                      |                              |                             |                               |
| Year published (2000–2020) (N=163):           |                |                             |                              |                             |                               |
| 2000–2005 29 (18)                             |                | 6 (4)                       | 0.61                         | 5 (3)                       | 0.33                          |
| 2006–2010 40 (24)                             |                | 10 (7)                      |                              |                             |                               |
| 2011–2015 45 (28)                             |                | 6 (4)                       |                              |                             |                               |
| 2016–2020 49 (30)                             |                | 10 (7)                      |                              |                             |                               |
| Published (N=163):                            |                |                             |                              |                             |                               |
| Pre ABC-02(11) (up to 2009) 58 (36)           |                | 13 (9)                      | 0.58                         | 7 (5)                       | 0.62                          |
| Post ABC-02(11) (after 2009) 105 (64)         |                | 19 (13)                     |                              |                             |                               |
| Impact factor of journal (N=163):§            |                |                             |                              |                             |                               |
| 0 ≤5 81 (50)                                  |                | 18 (12)                     | 0.71                         | 8 (5)                       | 0.63                          |
| >5–≤10 43 (26)                                |                | 6 (4)                       |                              |                             |                               |
| >10–≤15 1 (1)                                 |                | 1 (1)                       |                              |                             |                               |
| >15–≤20 19 (12)                               |                | 5 (3)                       |                              |                             |                               |

Continued
The gender of all authors were known, there were 1378 total authors and 352/1378 (25.5%) were women.

The geographic location of the home institution of the first and senior authors was Asia (42%/42%), Europe (29%/29%), USA (24%/22%) and other (4%/6%), respectively. Geographic location was significantly associated with the gender of the senior author. There were more female senior authors with home institutions in ‘other’ geographic locations (40% in 10 trials) ($\chi^2$ p=0.02) versus Asia (6% female senior authors, log p=0.01), Europe (8% female senior authors, log p=0.02) and USA (14% female senior authors, log p=0.08).

The median percentage of female author representation in publications was 25%; there were no female authors in 15 (13%) trials of 113 where all gender of authors was known (eight and seven trials were published pre and post-ABC-02, respectively; geographic location of home institution of first and senior authors for these 15 trials was Asia and Europe in 11 and 4 trials respectively).

Overall, female first and senior author representation was 20% and 10%, respectively. The gender of the first and last author was unknown for 12 (7%) and 9 (6%) publications, respectively (figure 2). The median position for female authors was second in all publications. The mean position of the first female author was 3.06 (SD 3.77) (the maximum number of authors in any publication was 33). If there was a male first author, the first time that a female author name appeared was more likely to be in the second position (29% of women in second author position) ($\chi^2$ 9.05, p<0.001). There was no association between the senior author gender and female authors being in the second author position ($\chi^2$ 0.06, p=0.80). There were only four female authors in the second last position of 113 trials where all author genders were known (all first and senior authors in these four relevant papers were men).

In publications with IF $\leq$5 and $>$5, there were 25% and 12% female first authors, and 11% and 8% female senior authors, respectively. In journals with higher IFs, female authors were particularly less likely to hold the first or senior author position. In publications with IF $\leq$20 and $>$20, there were 22% and 16% female first authors, and 13% and 0% female senior authors, respectively.

A variety of trial and journal factors were analysed for their association with author gender in the first and senior positions. The disease site, treatment setting, treatment modality, phase of trial, whether it met its primary end point, trial industry funding, year published, published

| Trial characteristics | Number (N) (%) | Female first author, N (%)* | Female first author, P value | Female senior author, N (%)† | Female senior author, P value |
|-----------------------|---------------|----------------------------|-----------------------------|-----------------------------|-----------------------------|
| $>$20–$<$30           | 4 (2)         | 1 (1)                      |                             |                             |                             |
| $>$30                 | 15 (9)        | 2 (1)                      |                             |                             |                             |
| Binary impact factor of journal (N=163): |              |                            |                             |                             |                             |
| $\leq$20              | 144 (88)      | 30 (20)                    | 0.54                        | 18 (12)                     | 0.1                         |
| $>$20                 | 19 (12)       | 3 (2)                      |                             |                             |                             |

*Where gender of first author known (N=151).
†Where gender of senior author known (N=154).
‡Other: Australia, Canada, Africa, South America, Mixed countries.
§Journal Citation Reports (Clarivate Analytics 2020). Due to rounding, percentages may not total 100%. $\chi^2$ tests were used to assess factors associated with female first and female senior authorship. Differences were considered to be statistically significant at p<0.05. Log regression was performed if $\chi^2$ p value was <0.05.

BTC, biliary tract cancer; NA, not available.

Figure 2  Gender of first (A) and senior (B) authors in phase II/phase III systemic clinical trial publications in biliary tract cancer.
DISCUSSION

Female first (1 in 5) and female senior (1 in 10) author representation in published later phase systemic clinical trial publications in BTC is low and has not changed significantly over the last two decades. This is in contrast to publications in HPB surgery, where female first author representation increased approximately 10% over a 10-year period, and to authorship in academic gastroenterology journals, where female first and senior authorship increased by approximately 20% (9.1% to 29.3%) and 10% (4.8% to 14.5%), respectively, from 1992 to 2012. The underlying reasons for the gender imbalance in later phase trial publications in BTC and lack of change over 20 years are not clear.

In the current study, there were more female senior authors associated with ‘other’ geographic locations (Australia, Canada, Africa, South America) versus Asia, Europe, and USA. This trend was also reported in the analysis of authorship in HPB surgery manuscripts, where articles published in North America were more likely to have a female first or female senior author compared with publications from Asia or Europe.

The proportion of women specialising in BTC (systemic) academic oncology is not known, and, therefore, one cannot comment definitively on whether the values for female first and senior author representation in later phase systemic clinical trial publications are proportional to the numbers of female providers practicing in this field. In addition, one cannot comment as to whether the percentage of women working within the BTC speciality has increased over the study period. This data are not readily available, as organisations such as the American Society of Clinical Oncology (ASCO) do not specifically mandate completion of speciality interests in membership documentation, and in the area of cancer specialisations, gastrointestinal oncology is included, but not BTC specifically. From the data collected in this current study, approximately one quarter of the entire cohort (where gender was known) were female authors, with 1/5 and 1/10 being first and senior authors, and so this share of female coauthors may be an estimate of the share in this speciality field.

The gender gap is not confined to authorship in the field of oncology. Gender differences have also been noted in relation to oral research presentations at major conferences (ASCO and European Society for
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Medical Oncology (ESMO)). Of 2425 contributing authors to consecutive abstracts of all plenary sessions of the ASCO annual meeting and ESMO presidential sessions between 2000 and 2018, 28% of authors and 21% of presenters were women. The gender balance of speakers and scientific members of four major oncology conferences in China between 2009 and 2019 demonstrated a similar pattern; the number of eligible female speakers in the denominator of all potentially eligible speakers was not known and was cited as a limitation. Therefore, taken together, potentially eligible speakers was not known and was cited as a limitation. Consequently, the number of presenters was not known and was cited as a limitation. Richter et al. recently analysed data from the Association of American Medical Colleges on all medical school graduates from 1979 to 2013 (N=5 59 098) and faculty data up to 2018. They compared the percentages of women who would have been expected to be promoted on the basis of the proportion of women in the graduating classes, with the actual percentages of women promoted. In academic medical centres, female physicians were found to be less likely than men to be promoted to associate (HR 0.76, 95% CI 0.74 to 0.78) or to full professor (HR 0.77, 95% CI 0.74 to 0.81) or to be appointed to department chair (HR 0.46, 95% CI 0.39 to 0.54), and there was no change over 35 years.

There are limitations associated with the current study, such as the inability to assign all names to a gender, lack of data on academic rank, qualifications and which authors were principal/chief investigators within institutions. Information on productivity for the entire cohort of author collaborators, which may have an impact on first or senior authorship, could not be collected accurately, as it was not possible to determine this retrospectively from the time of manuscript publication (if using the Hirsch-index as a metric of scholarly activity, for example), and, in addition, all individuals did not have fully accessible scientific social site profiles. This topic could be the focus of future research in a prospectively designed study in this disease group speciality. It was also not possible to determine the number of unique female/male authors in the total sample size due to non-availability of gender information for the entire authorship, and so one cannot comment accurately on the entirety of gender of the population of academics conducting these trials. Also, it was not possible to identify non-binary or transgender authors. In addition, secondary publications of the relevant trials were not included, nor were associated laboratory-based research outputs from the trials, and it is also possible that some relevant publications may have been missed. However, to the authors’ knowledge, this is the first study examining the gender representation in authorship in published later phase systemic clinical trials in BTC, and included sequential global publications over a 20-year period, identified by a librarian with expertise in comprehensive search strategies.

It has been reported that peer-reviewed publications with gender-heterogeneous authorship received 34% more citations than publications produced by gender-uniform authorship groups, and authorship diversity should be encouraged. An ESMO Women for Oncology committee survey exploring gender-related challenges facing oncologists concluded that the initiatives needed to address under representation of female oncologists in leadership roles should include enhanced promotion of work-life balance, development and leadership training and additional support for flexible working.

In conclusion, this study highlights the paucity of female authors in first and senior positions in later phase BTC systemic oncological clinical trial publications, acknowledging the lack of information on gender proportionality in this specialist field. Prospective studies incorporating productivity measures may be more definitively informative. For change to happen, a problem needs to be identified. This manuscript has aimed to highlight discrepancies in gender of authorship in one disease speciality. It is hoped that the recognition of this imbalance will stimulate formulation of solutions to counter this potentially damaging trend. Could it be that women are carrying an excessive load of non-promotable work, which is holding them back from concentrating on tasks that may forward their academic career? Exploration of this concept in individual institutions may be revealing and may require conducting research in this particular specialist area (e.g., exploration of who is performing non-promotable tasks). If this is found to be the case, then changing the landscape of non-promotable tasks is warranted, with the potential for release of researcher time to concentrate on work which is considered promotable.

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