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Review

Infectious risk of endovaginal and transrectal ultrasonography: systematic review and meta-analysis

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SUMMARY

Background: Appropriate endovaginal/rectal ultrasound transducer disinfection has been an ongoing and vexed question in gynaecology, obstetrics and urology. However, the routine use of probe covers followed by low-level disinfection (wipes/spray) is usually applied between patients in some countries (e.g. France).

Aim: To perform a systematic review and meta-analysis of the scientific literature in order to identify case reports of contamination following endovaginal/rectal probe use, and to estimate the infection prevalence related to the use of these probes in common daily practice.

Methods: Systematic review and meta-analysis.

Results: From the 867 potentially eligible references, 32 articles were finally included. Very few cases with an established route of contamination had been reported. Indeed, apart from occurrence of outbreaks, it is difficult if not impossible to detect viral contamination through the use of endovaginal/rectal ultrasound probes. However, there was a pooled prevalence of 12.9% (95% confidence interval: 1.7–24.3) for pathogenic bacteria, and 1.0% (0.0–10.0) for frequently occurring virus (human papillomavirus, herpes simplex virus, and cytomegalovirus) for endovaginal/rectal probes, both after low-level disinfection. The pooled prevalence of infected patients after transrectal ultrasound and guided biopsies was estimated to be 3.1% (1.6–4.3).

Conclusions: There appears to be a risk of transmitting bacterial or viral infections via endovaginal/rectal ultrasound transducer, and the present meta-analysis provides an estimate of this risk. Further research with sophisticated modelling is warranted to quantify the risk.

Introduction

Appropriate ultrasound transducer disinfection has been an ongoing and vexed question, and hygiene of ultrasound probes continues to be discussed in gynaecology, obstetrics and urology. The cost of transducers precludes a single-use-only strategy. The key infection control issue concerns the risk of contamination and the need for specific cleaning/disinfection procedures to ensure a high degree of protection against infectious disease transmission, even when a disposable cover is used. Endovaginal and transrectal ultrasound are considered as at least medium-risk procedures involving contact with mucous membranes.[1–3] The main pathogens of concern are human immunodeficiency virus (HIV), cytomegalovirus (CMV), human papilloma virus (HPV), enteric Gram-negative pathogens (e.g. *Escherichia coli*, *Klebsiella* spp.), for both ultrasound examinations, and *C. difficile* more specifically for

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transrectal ultrasound, and gonorrhoea and syphilis for endovaginal ultrasound. Typically, the transducer head is protected with a sheath that can be made of latex, polyurethane, or another substance. Disposal of the cover is followed by cleansing and disinfection using a virucidal agent compatible with the transducer. If it does not damage the probe, the preferred method of disinfection is immersion (in either a low- or high-level disinfectant depending on the country). The most commonly recommended agents – glutaraldehyde, aldehydes and quaternary agents – are used because of transducer surface compatibility rather than the effectiveness of these agents' disinfecting properties. However, glutaraldehyde or other aldehydes are questioned because they may shorten the transducer life and because they can generate adverse events for workers and patients (i.e. chemical damage to the mucosa if the device is insufficiently rinsed), and for procedure (e.g. damage of gametes and embryos in the case of *in vitro* fertilization). If the probe cannot be immersed, wiping the probe with a disinfectant is the next best choice. Least desirable is applying the disinfectant with a swab, as it corresponds to low-level of disinfection.

The use of condoms as probe covers as means to avoid high-level disinfection is not recommended even though they present a lower rate of perforation compared to commercial probe sheaths. The overall rate of probe cover perforation is 1–9%. Nevertheless, every patient must be regarded as a potential source of infection. Because of the risk of disruption, recommendations in the USA, Canada and Australia insist on high-level disinfection of the probes.[1–4] However, it remains to estimate the infectious risk for the patient, especially as the procedure requires contact with mucous membranes.

We thus aimed to undertake a systematic review and meta-analysis to: (i) summarize the existing evidence of cases of infected patients related to the use of endocavitary ultrasound focusing on endovaginal and transrectal ultrasound; (ii) summarize and calculate a pooled estimate of probe contamination regarding bacteria and virus for endovaginal ultrasound after probe cover and cleaning procedures; and (iii) summarize and provide a pooled prevalence of the number of infected patients after transrectal ultrasound.

Methods

Study design

We performed a systematic review and meta-analysis, in accordance with the Center for Reviews and Dissemination guidelines for undertaking systematic reviews and PRISMA guidelines in order to: (i) identify case reports of infectious contamination due to endovaginal probe use; (ii) estimate the infectious risk related to the use of endovaginal probe in usual daily practice; and (iii) estimate the infectious risk related to transrectal ultrasound.[5,6]

Literature search

We searched Medline and Embase database for articles published from 1966 to July 2011. Duplicates were discarded using EndNote software to manage references. The search strategy used medical subject heading terms and text words, including the following keywords: 'needle/biopsy', 'endovaginal', 'transrectal', 'ultrasound', 'ultrasonography/methods', 'ultrasonography/instrumentation', 'ultraviolet rays', 'probe', 'transducers/microbiology'; 'transducers/virology', 'disinfection/methods', 'disinfection/administration & dosage', 'disinfectants/pharmacology', 'equipment contamination/prevention & control'; 'transducers/microbiology'; 'transducers/virology', 'cross infection/prevention & control', 'iatrogenic disease'. This search was supplemented with searching in the first two pages of related articles of the included articles, and with a manual review of reference list of all articles meeting inclusion criteria, and a manual review of the related articles of each included article. There was no *a priori* language restriction; articles were considered for inclusion when translation was easily accessible to authors (i.e. Spanish, Portuguese, German and French articles).

Study eligibility

Articles were included if they contained original data from a cohort, a clinical trial, a case series, or case report of patients for whom a bacterial and/or viral and/or fungal infection related to an endovaginal or transrectal ultrasound examination was reported. To achieve our second aim, we focused on cohort studies of patients who underwent either endovaginal or transrectal ultrasound, with bacteria and/or virus identified on the probe (before and/or after sheath removal). Studies were included if they reported original data from a cohort (part of randomized trial or not) of men who underwent transrectal ultrasound with a follow-up that included recording of infection. Case–control studies were not included. Articles that contained insufficient (more than 20% of missing data) or incomplete data also were not included.

Data identification and extraction

One reviewer assessed the title and abstract of each potential study from the list obtained by the electronic research and rejected it if it was clearly ineligible. In case of doubtful eligibility, the full text of the article was reviewed. All eligible articles were fully reviewed against inclusion/exclusion criteria in a random order. When the inclusion remained questionable, it was discussed with another reviewer; data from included articles were then extracted using a standardized electronic data extraction form covering study (type of design, consecutiveness of inclusion, country of origin), patient (gender, age), and article (author, journal, etc.) characteristics, the ultrasound disinfection techniques used (clean/dry; disinfectant/no disinfectant). If a disinfectant was used it was classified according to the guidelines of the US Centers for Disease Control and Prevention (CDC) and Hospital Infection Control Practices Advisory Committee (HICPAC).[7] Also recorded was whether probes were covered or not and the number of cores per patient in the case of transrectal biopsy. For case report and case series, full details of infection were collected. For cohort studies in order to estimate (i) the prevalence of contaminated probes after cleaning, or (ii) the prevalence of patients with infectious events after transrectal ultrasound, both the total number of included patients and of cases were extracted. Questions were resolved by discussion with another reviewer where necessary. Authors were contacted by e-mail in case of duplicate publication. In case of overlapping data from duplicate articles, data were only extracted from the most

recent and complete publication. An attempt was also made to contact authors if data presentation was incomplete or to resolve any apparent conflict or inconsistency in the article.

Statistical analysis

Pooled prevalences of contaminated probes and pooled prevalence of infected patients due to transrectal ultrasound were calculated by using a random effects model with inverse-variance weighting using the DerSimonian and Laird method.[8] In the random effects model, each study was weighted by standard error of an inverse variance method. Statistical heterogeneity between and within groups was measured by using the Q-test and the I^2 value. To quantify the extent of heterogeneity, the I^2 statistic was used to measure the percentage of variability among summary indices that were caused by heterogeneity rather than by chance. A study with an $I^2 > 50\%$ indicates substantial heterogeneity, that was explored, if necessary, using meta-regression and sensitivity analysis.[9] To evaluate the weight of particular articles on the pooled estimates, we performed influence analysis: this method recalculates the pooled prevalence estimate while omitting one study at a time. In addition, we used cumulative meta-analysis to examine the effect of year of publication on the results. Finally the presence of a publication bias was assessed visually by examining funnel plots and by using the Egger test.[10]

Results

Characteristics of studies

The electronic search identified 867 references, after having discarded duplicates (Figure 1). Based on the title or abstract, 62 references were considered as potentially eligible. The manual review and the discussion with experts identified eight extra references for a total of 80 potentially eligible articles. After reading the full text, we included four reports of cases or case series of infections related to endovaginal or transrectal ultrasound; four articles on microbial contamination of endovaginal ultrasound probes and 24 cohort studies of patients who had developed infection after transrectal ultrasound. A total of 32 articles was included (Figure 1).[11–42]

Those studies ultimately included were all published between 1993 and 2011 (median year: 2006; interquartile range: 2001–2008; mean year: 2004; SD: 5). Briefly, 10 (31%) studies were performed on the American continent, 15 (47%) in Europe, 6 (19%) in Asia, and one (3%) in India. All articles were written in English. The characteristics of the included studies, apart from case reports and case series, are detailed in Table I.

Case reports of infected patients

Only four articles were found to report infection that had been related (or suspected) to the use of endocavitary ultrasound, following suspicion of an outbreak and investigation as to how patient-to-patient transmission could have occurred. Gaillot *et al*. reported an outbreak of *Klebsiella pneumoniae* among eight women who had undergone endovaginal ultrasound in the emergency room.[11] One patient gave birth to a neonate who presented with neonatal sepsis. The outbreak originated from a contaminated ultrasound coupling gel. In 2004, Hutchinson *et al*. reported an outbreak of *Burkholderia cepacia* infection in six men who had all undergone transrectal ultrasound using contaminated ultrasound gel.[12] All presented with urinary tract infection, three of them had in addition blood cultures which grew *B. cepacia*. Gillepsie *et al*. then reported four patients hospitalized with *Pseudomonas aeruginosa* infection after outpatient transrectal ultrasound-guided biopsy.[13] The review of the reprocessing procedures revealed that biopsy needle guide was disinfected by submersion in high-level disinfectant rather than sterilization, as recommended by the manufacturer. After disinfection, the guide was rinsed with non-sterile tap water. Lastly, Lesourd *et al*. published two cases of undoubted patient-to-patient hepatitis C virus (HCV) transmission following assisted conception.[14] Although endovaginal ultrasound was initially incriminated, the complete investigations demonstrated that the most likely route of infection was deemed to be through healthcare workers.

Contamination of endovaginal ultrasound probes

Four studies analysed bacterial and viral contamination of endovaginal probes after patient use, and after cleaning procedures before the following patient.[15–18] All were prospective studies; three of them were single-centre. All used a routine not high-level disinfection procedure for their ultrasound endocavitary probes (i.e. after disposing of the probe cover): a two-step process consisting of cleaning with a dry towel, then either with a towel impregnated with a disinfectant spray or a pre-impregnated towel with disinfectant. Two studies ($N = 512$) investigated the prevalence of bacterial contamination of probes after sheath removal: pooled prevalence of 33.7% (95% CI: 20.3–47.9) (Figure 2). On pooling data on bacterial contamination after cleaning procedures from the four studies ($N = 596$), the pooled prevalence was 12.9% (95% CI: 1.7–24.3). The bacteria concerned were *Enterobacter* spp., *Acinetobacter* spp., *P. aeruginosa*, *B. cepacia*, *E. coli*, *Staphylococcus aureus*. Two studies investigated the presence of virus: herpes simplex virus, CMV, HPV on 408 probes.[14,15] After removal of the probe sheath, 19.4% (95% CI: 13.7–24.0) of the probes sheaths were contaminated; and 1.0% (95% CI: 0.0–10.0) of the probes remained contaminated. None of the four meta-analyses showed heterogeneity ($I^2 = 0\%$, $P = 1.0$); thus no meta-regression nor influence analysis was conducted. Neither the funnel nor Egger's test found significant evidence for missing articles; however, they are not sufficiently powerful for this small number of studies.

Infected patients after transrectal ultrasound with or without biopsy

Twenty-four studies were included, representing a total of 24,627 patients.[17–40] Eighteen (75%) were prospective studies, 23 (96%) were single-centre studies. In all articles, condoms or sheaths were used to cover the probe, as well as ultrasound gel, and 6–15 cores/per patient were performed. To prevent infection, antibiotics (fluoroquinolones in all cases) were given in 13 (72%) of the studies with a short course of 1–5 days before the procedure and associated biopsies. In all, 380 patients were reported as having infectious complications: in 10 (45%) studies, infections were not detailed, five (23%) focused on acute prostatitis and epididymitis, four (18%) on urinary tract

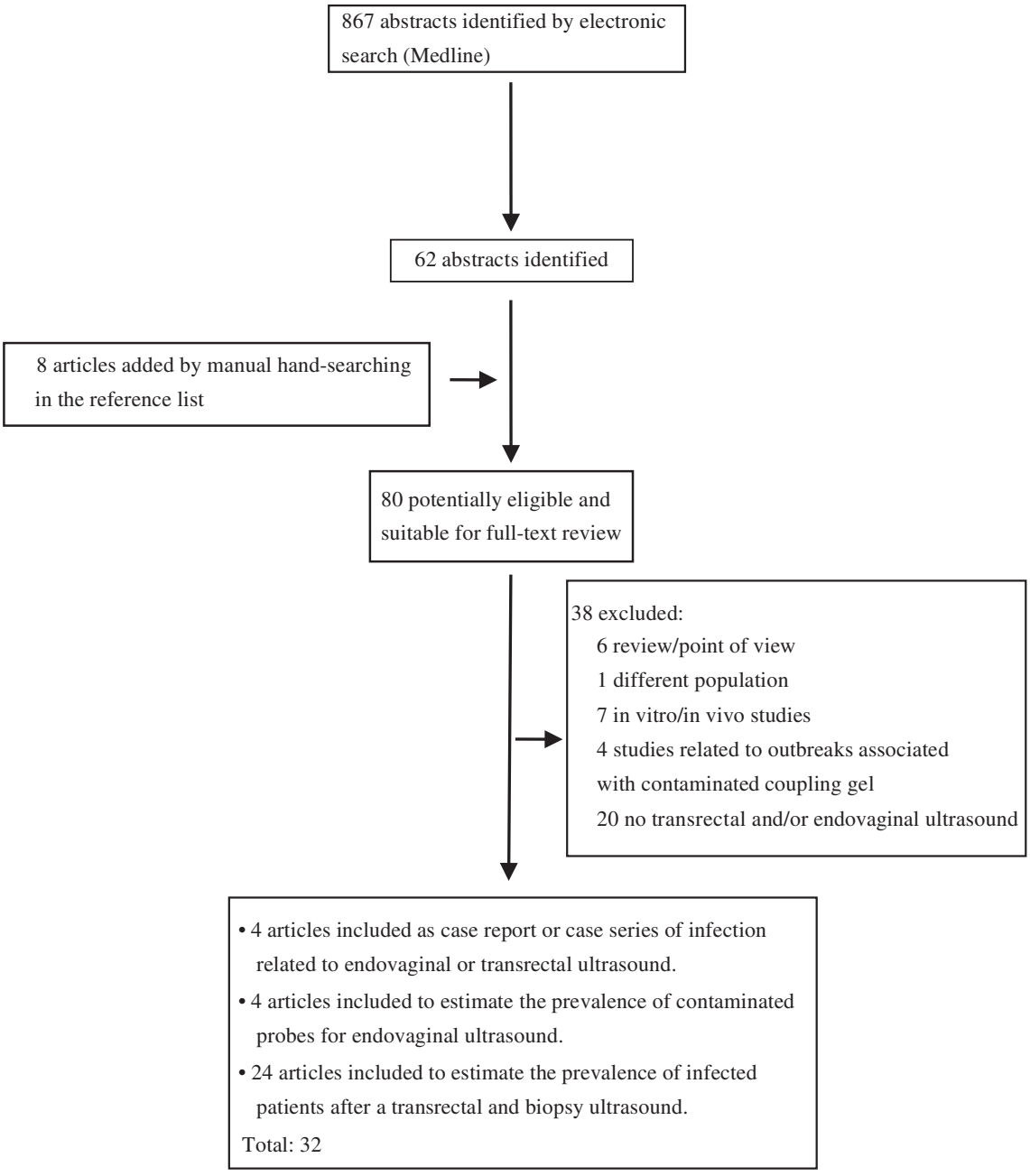

Figure 1. Results of electronic search.

infection, and three (14%) involved sepsis. The pooled prevalence of infection was 3.1% (95% CI: 1.6–4.3; Figure 3). No evidence of heterogeneity was found: $I^2 = 0\%$; $P = 1.0$. Therefore, we did not run meta-regression. The influence analysis confirmed that none of the articles had a particular weight that might have influenced the meta-analysis and the pooled estimate. No evidence of missing articles was found graphically with the funnel plot, nor statistically by Egger's test.

Discussion

To our knowledge, we performed the first systematic review and meta-analysis on the infectious risk related to endovaginal and transrectal ultrasound. First, we confirmed that very few cases with an established route of contamination had been reported. Indeed, apart from occurrence of outbreaks, it is difficult if not impossible to detect viral contamination through the use of endovaginal/rectal ultrasound probes, because the infections are so numerous (CMV, HSV, HPV); so infrequent (HIV, HBV, HCV) or because the route of transmission is unknown (HCV). An attempt to estimate the number of infected people by endovaginal ultrasound probes has been made by the French Sanitary Institute (INVS).[43] However, the modelling techniques used were relatively crude, applying a multiplicative model, assuming that an infected patient would only infect the following one, and not taking into account how probe covers and their manipulation before cleaning the probe would

Table I
Characteristics of the included studies

Authors	Year	Country	*N*	Design	Type of infection	Antibiotics given
Keizur *et al.*[24]	1993	USA	272	Retrospective	Sepsis, *Burkholderia cepacia*	No
Enlund and Varenhorst[21]	1997	Sweden	426	Prospective	Fever	No
Sieber *et al.*[39]	1997	USA	4439	Prospective	UTI	Yes
Rodríguez and Terris[34]	1998	USA	128	Prospective	Infection	N/A
Aron *et al.*[19]	2000	India	231	Prospective	Infection	Yes
Griffith *et al.*[22]	2002	USA	400	Prospective	UTI	Yes
Raaijmakers *et al.*[33]	2002	The Netherlands	5802	Prospective[a]	Infection	N/A
Berger *et al.*[41]	2004	Austria	4303	Prospective	Fever	N/A
Donzella *et al.*[20]	2004	USA	739	Prospective	Epididymitis	Yes
Otrock *et al.*[30]	2004	Lebanon	207	Retrospective	UTI	Yes
Sabbagh *et al.*[35]	2004	Canada	363	Prospective	Infection	Yes
Sheikh *et al.*[36]	2005	Kuwait	300	Prospective	Septicaemia	Yes
Lee *et al.*[27]	2006	UK	100	Prospective	Infection	N/A
Puig *et al.*[32]	2006	Spain	1018	Prospective	Major and minor infection	Yes
Shen *et al.*[37]	2006	China	80	Retrospective	Infection	No
Feliciano *et al.*[42]	2008	USA	1273	Prospective	Fever	Yes
Lessa *et al.*[28]	2008	USA	528	Prospective	Infection	No
Miura *et al.*[29]	2008	Japan	665	Retrospective	Septic shock	Yes
Shigehara *et al.*[38]	2008	Japan	457	Prospective	Acute prostatitis	Yes
Yamamoto *et al.*[40]	2008	Japan	243	Prospective	Acute prostatitis	N/A
Hadway *et al.*[23]	2009	UK	256	Prospective	Urosepsis, bacteraemia	Yes
Ozden *et al.*[31]	2009	Turkey	1339	Retrospective	Acute prostatitis	Yes
Kim *et al.*[25]	2010	Korea	878	Retrospective	Acute prostatitis, sepsis, bacteraemia	No
Koc *et al.*[26]	2010	Turkey	180	Prospective	UTI	N/A
Amis *et al.*[15]	2000	UK	72[b]	Prospective	Bacteria/virus on the probe	—
Syles *et al.*[17]	2006	UK	50[b]	Prospective	Bacteria on the probe	—
Bataillon *et al.*[18]	2010	France	34[b]	Prospective	Bacteria on the probe	—
Kac *et al.*[16]	2010	France	440	Prospective[a]	Bacteria/virus on the probe	—

N/A, not available; UTI, urinary tract infection.
[a] The studies by Koc *et al.* and Raajmakers *et al.* were multi-centre, all others, single-centre.
[b] Number of probes studied.

affect the amount of virus or bacteria left on the probe head. Therefore, the INVS conclusions on safety regarding the current disinfection procedures for endovaginal ultrasound probes may raise some concerns, and should be debated. Indeed, this modelling would be more elaborate, focusing on viral and bacterial quantitative variation across the patient flow, and depending on (i) the order of infected (or uninfected) patients, (ii) the micro-organism's ability to stay on the probe after cover removing. This could then be turned into an infection risk for patients. However, many assumptions would have to be made, with no possible check for many of them, and difficulties when assessing and validating the derived model. Interestingly,

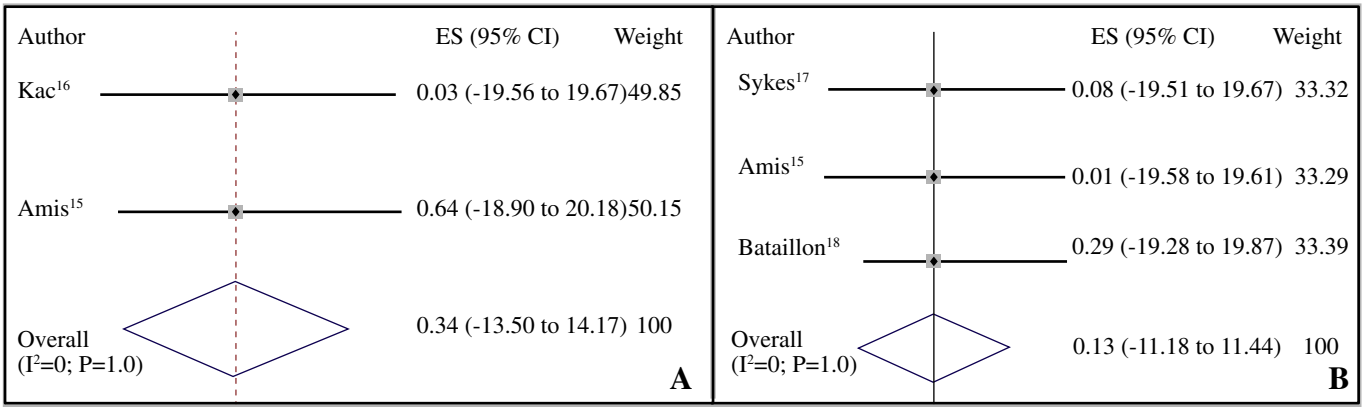

Figure 2. Forest plots showing the prevalence of contaminated probes with pathogenic bacteria (A) after removal of the probe sheath (two studies, $N = 512$ examinations), (B) after the cleaning procedure (four studies, $N = 596$ examinations) (one study[14] did not appear on the plot because of zero events, but was included in the pooled calculation). ES, estimate; CI, confidence interval.

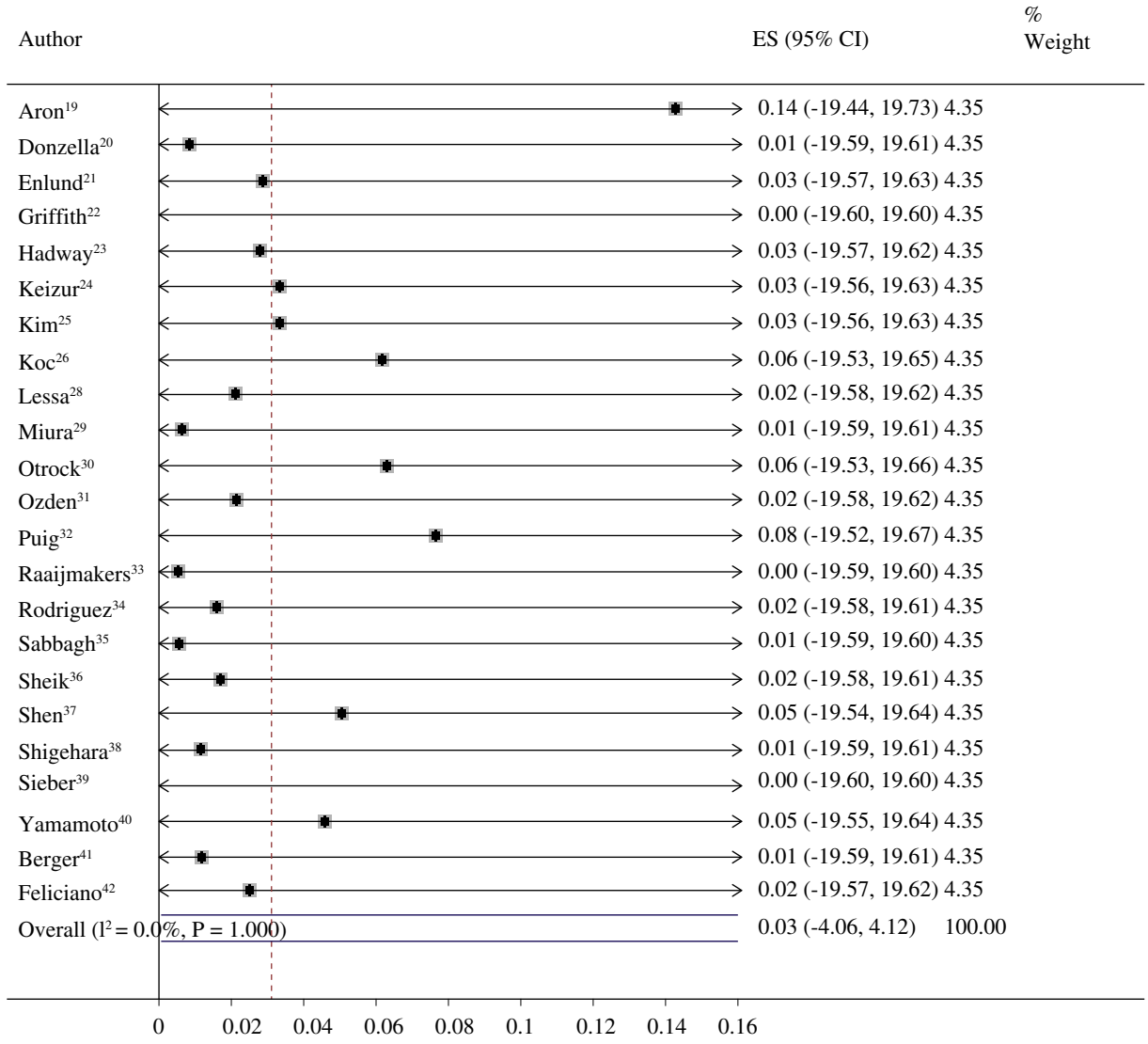

Figure 3. Forest plot showing the prevalence of patients with infectious complications after a transrectal ultrasound and guided biopsies. Weights are from random effects analysis. ES, estimate; CI, confidence interval.

Gaillot *et al.* and Hutchinson *et al.* stressed that not only could the ultrasound probes be vectors of infection but also that ultrasound gel may be a source of bacterial contamination leading to potentially severe infection.[11,12] This means that disinfection procedures should include both probes and gel bottles, as well as regular infection controls.

Second, this study found a pooled prevalence of 12.9% (95% CI: 1.7–24.3) for pathogenic bacteria, and 1.0% (95% CI: 0.0–10.0) for widespread viruses (HPV, HSV, and CMV) after cleaning procedures corresponding to routine disinfection procedures, which are not high-level quality. This result reflects only what can be found on the head of the probe, not how infectious the endovaginal ultrasound might be. However, it is interesting to demonstrate that the current disinfection procedures do not provide a perfect cleaning method as recommended by CDC guidelines.[7] One could argue that, even if some virus or pathogenic bacterium may remain on the probe, a new cover (condom or sheath) should be applied for the next patient. Unfortunately, the global rate of probe cover perforation is 1–9%, and contamination by the micro-organisms remaining on the probe head after cleaning procedures, despite a new cover, to the following patient would be possible.[44,45] Of course, this risk needs to be assessed and estimated, using a modelling approach in the absence of relevant study.

Third, we estimated the pooled prevalence of infected patients after transrectal ultrasound and guided biopsies to be 3.1% (95% CI: 1.6–4.3). However, there is in some cases an attempt to specify the precise cause of infection: Hutchinson *et al.* considered the route of contamination in their four cases to be the result of a lack of sterilization of the needles for biopsy.[12]

Moreover, combining dry towel and towel with disinfectant for cleaning the probe head for endocavitary ultrasound is not the only method of disinfection. High-level disinfection techniques exist, but require time between patients to apply; this may explain why it is not commonplace in current practice. However, new procedures based on ultraviolet C (UVC) or on hydrogen peroxide use are in evaluation, and could find a real

place in the cleaning process of ultrasound probes. For the moment, efficacy regarding bacterial and viral cleaning has been assessed, but impact studies are needed to establish clear protocols of UVC use, as well as for other alternative disinfection strategies, in the whole process of probe disinfection.[16]

Evidence of infectious risk of bacterial and viral transmission related to the current probe between patient cleaning procedures does exist, even if no HIV, HBV, and HCV transmitted infections have been found and reported according to this systematic review. However, it does not mean that such a risk does not exist, and infection control practice should be guided by publication of outbreaks and cross-infection incidents, as well as by a basic consideration of the risk of potential pathogens remaining on the probe between patients. In similar medical practices, such as dentistry, some models have estimated the infectious risk related to HIV, HBV and HCV as infinitesimally low.[46] However, the modelling seems to us oversimplistic, especially regarding the absence of serial assumption, and more sophisticated and robust modelling has to be performed to provide an estimate of the infectious risk for potential pathogens for which no reported data are available. Common sense regarding the potential risk of contamination should lead to higher-level disinfection between probe uses whatever the evidence currently published and available.

To conclude, we found evidence that the infectious risk of bacterial or viral transmission does exist, and the present meta-analysis provides estimates for some parts of the overall process. Further research with sophisticated modelling is warranted to specify this infectious risk with a different approach. Combining meta-analysis with mathematical modelling would be helpful to give more confidence when drawing conclusions, before making public health decisions if necessary.

Conflict of interest statement
None declared.

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